EXHIBIT 1

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	: MDL NO. 2875 : : : VIDEOTAPED DEPOSITION : UPON : ORAL EXAMINATION : OF : STEPHEN S. HECHT, PhD

TRANSCRIPT of the stenographic notes of the proceedings in the above-entitled matter, as taken by and before ELLEN J. GODINO, CCR, RPR, CRCR, held via ZOOM VIDEOCONFERENCE from various locations, with the witness located at 2231 6th Street, Minneapolis, Minnesota, on Friday, January 13, 2023, commencing at 8:18 a.m. Central Time.

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I N D E X

INDEX (Continued)

EXHIBITS

E X H I B I T S (Continued)

E X H I B I T S (Continued)

E X H I B I T S (Continued)

Page 10

THE VIDEOGRAPHER: Good morning. We are going on the record at 8:18 a.m. Central Time on January 13, 2023. Please note that this deposition is being conducted virtually. The quality of recording depends on the quality of camera and internet connection of participants. What is seen from the witness and heard on screen is what will be recorded. Audio and video recording will continue to take place unless all parties agree to go off the record.

This is Media Unit 1 of the video-recorded deposition of Dr. Stephen Hecht in the matter of In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation, filed in the United States District Court for District of New Jersey, Camden Vicinage, MDL Number 2875.

My name is Lee Bowry, from the firm of Veritext New Jersey, and I am the videographer. The court reporter is Ellen Godino, and our concierge is Justin Biley, also with Veritext.

I am not related to any party in this action, nor am I financially interested in the outcome.

If there are any objections to proceeding, please state them at this time.

Page 11

Having heard none, counsel attending remotely will be noted on the stenographic record.

Will the court reporter please swear in the witness and then counsel may proceed.

S T E P H E N H E C H T, Ph.D., 2231 6th Street, Minneapolis, Minnesota, having been duly sworn, testified as follows:

EXAMINATION BY MR. BERNARDO:

Q. Good morning, Dr. Hecht. Would you please state your name for the record?

A. Pardon? I couldn't hear you.

Q. Well. I'll adjust my volume. Can you hear me if I speak at this volume?

A. Yeah.

Q. Okay. Would you please state your name for the record?

A. Stephen Hecht.

Q. And you understand, Dr. Hecht, that you're here today under oath, as if you were in a courtroom, and testifying as if you were in a courtroom. Correct?

A. Yes.

Q. And I know you've been deposed a number of times, so I'm not going to go through the standard preamble, but I just want to say that I'm going to assume that you understand the questions I'm asking, unless you ask me to clarify. Is that fair?

Page 12

A. Okay.

Q. Is there anything that would prevent you from providing truthful and accurate testimony today?

A. No.

Q. Okay. And I know you're -- we're all doing this through technology, and I trust that you're not going to communicate to anybody or look at communications from anybody, either by email or chat or text or otherwise, during the course of my questions. Is that fair?

A. Yes.

Q. Dr. Hecht, you've written two reports in this case. One is dated July 21 -- I'm sorry, July 6, 2021, and one is dated October 31st, 2022. Correct?

A. Yes.

MR. BERNARDO: I'd like to mark those two exhibits as Hecht-1 and 2?

MR. SLATER: Which one is 1?

MR. BERNARDO: His first report -- thank you, Adam -- July 6, 2021, will be 1; and October 31st, 2022 will be 2.

(Exhibit Hecht-1, Letter Report of

Page 13

Stephen S. Hecht, Ph.D., dated July 6, 2021, No Bates Stamps, 44 Pages, was received and marked for identification.)

(Exhibit Hecht-2, Letter Report of Stephen S. Hecht, Ph.D., dated October 31, 2022, No Bates Stamps, 15 Pages, was received and marked for identification.)

Q. And I understand, Dr. Hecht, you may have copies of those reports with you. And just to clarify the questions I'm going to ask you: I'm going to be asking you about your 2022 report, Exhibit 2, in its entirety, but I'm only going to be asking you about certain portions of your 2021 report; and it would be the Section Roman II.2, titled "Formation of Nitrosamines" on pages 6 to 7, if you want to just take a look at that.

A. Yes.

Q. And then all of Section Roman III, titled "Formation of Nitrosamines in Valsartan API."

(Court Stenographer clarification.)

Q. Section III, titled "Formation of Nitrosamines in Valsartan API."

A. Section III?

Q. And I'm doing this, Dr. Hecht, just to be efficient here. So when I just ask about your

Page 14

opinions in this case or your opinions or your report, I don't want to go through this clarification. I just want you to assume, unless I state otherwise, that those are the sections of your first report and the entirety of your second report about which I'm asking. Is that clear?

A. No.

Q. Okay.

MR. SLATER: Rich, I think this is -- I get what you're saying, but I think this is very confusing. Because you're going to make him think he's got to go look at --

A. I'm not sure what you mean by "Section 3."

Q. There's a section, Roman III?

MR. SLATER: What page?

MR. BERNARDO: Give me a minute.

MR. SLATER: Page 18 of the first report.

Q. And while you're looking at that, Dr. Hecht, the reason I'm doing this is, I just don't want there to be confusion, and this goes to a point that Mr. Slater raised. I'm really here asking you questions about certain opinions.

And I just, when I say "your opinions in

Page 15

this case" or "your report," I'm really referring to these confines. I just want that to be clear on the record, and for you to understand that so we're not talking about either general caution or other issues.

Does that help clarify?

A. Yes.

Q. Okay. Thank you very much.

And Dr. Hecht, did you sign -- we're going to be talking about exhibits that have been marked "Confidential" in this litigation.

Have you signed the appropriate exhibits to the protective order in this case? Are you familiar with the protective order that has been entered in this litigation?

A. No.

MR. SLATER: Yes, he signed it, Rich. This was years ago.

MR. BERNARDO: Okay. I just want a clarification for that on the record, and he just said something different than you did.

Q. So let me ask you that again. There's a protective order that's been entered in this case that governs the use of confidential information. I just want to ensure that you've read that, and that you have signed on it, intending that you agree to

Page 16

its terms?

A. Okay.

Q. So is "okay" a "yes"?

A. Yes.

Q. Thank you.

Dr. Hecht, you agree ZHP used four distinct manufacturing processes to produce valsartan API, prior to 2018. Fair?

A. Yes.

Q. And the first one is known as the TIN process?

A. Yes.

Q. And the second is known as the TEA process?

A. Yes.

Q. And the third is a TEA with quenching process?

A. Yes.

Q. And the fourth is the zinc chloride process?

A. Right.

Q. Okay. Let's talk about those processes. Let's start with the TIN process.

And if you need me to pull up documentation in order for you to answer these

Page 17

questions, please ask and I'm happy to do that and have that marked, but I think some of these, you should be able to answer without having to look at them.

So let's talk about the TIN process. In that process -- that's what the company refers to -- in that process, in company documents, there is a reference to "Step 4, the carbon-nitrogen group or CN starting material, which was treated with sodium azide to form the tetrazole compound." Is that correct?

A. Yes.

Q. Okay. And in simple terms, what is a tetrazole compound?

A. The tetrazole has four nitrogens in a ring structure, and it's part of the structure of the sartans.

Q. And the --

A. The sodium azide provides three of the nitrogens.

Q. And this process was done in the presence of a catalyst, [redacted] using [redacted] as a solvent?

And pardon me if I'm not pronouncing these exactly correctly, but I think you'll get the

Page 18

gist?
A. It's [redacted]
Q. Thank you.
(Court Reporter Clarification.)
MR. BERNARDO: Sure.
Q. Let's switch over to the TEA process.
ZHP filed a paper submission, which is called the Drug Master File, with the FDA for the TEA process in January of 2010. Correct?
A. Yes.
Q. Okay.
MR. BERNARDO: Let's pull up on the screen and mark as Exhibit 3 company documents regarding the product development report.
MR. BILY: Counsel, what tab?
MR. BERNARDO: Tab 3.
(Exhibit Hecht-3, FDA Receipt Letter for ZHP Drug Master File Submission, Bates SOLCO00032578 through 32580, was received and marked for identification.)
Q. Can you see what's on the screen?
A. No, it's too small.
MR. BERNARDO: Can you expand the size?
Q. Does that help?
A. Yeah, that's a little better.

Page 19

Q. Okay. Have you seen this document before?
MR. SLATER: Sorry, Rich, can we see the Bates number?
MR. BERNARDO: Sure.
MR. SLATER: If someone can just scroll to the Bates number.
MR. BERNARDO: And it's SOLCO 00032578, and we're on page 1.
MR. SLATER: Thank you.
A. Yeah, I don't remember.
Q. You don't remember whether you've seen this document before?
A. No.
Q. I will represent to you that this is, as you can see from it, a document sent to the Food and Drug Administration assigning a number of a submission by ZHP on January 22nd, and the title of the submission is "Valsartan Process As Manufactured."
Are you familiar with this type of document?
A. With this type of document? Is that what you said?
Q. Yes, that was my question?

Page 20

A. I'm not terribly familiar with it, no.
Q. Okay.
A. But I can see what -- I can understand what it is.
Q. So this isn't the kind of document you would have looked at to form your opinions in this case, as to the manufacturing changes or the reason for changes, or the process?
MR. SLATER: Objection to the form of the question.
You can answer.
A. Not directly from this document. I mean, I've read descriptions of the -- you know, the processes that were used.
Q. And where did you get the descriptions, and what kind of documents did you get the descriptions of the processes that were being used, Dr. Hecht?
A. From the -- well, I've seen the, you know, the documents from ZHP that describe a lot of this. And also...
Q. Why don't you turn to the next page --
A. I don't know where I saw them.
Q. If we can scroll to the next page. And further --

Page 21

MR. BERNARDO: Can we go off record for one minute.
THE VIDEOGRAPHER: Going off the record. The time is 8:30 --
MR. BERNARDO: Oh --
THE VIDEOGRAPHER: Did you not want to go off the record?
MR. BERNARDO: I think we can resolve this. I want my colleague to share the documents, not the videographer, so that I can direct and be efficient and show him pages. I also wanted to resolve it at a break, so he can look at things, so we don't have to do this, because I think these are documents with which he's familiar, and this is going to take us a long time, if this doesn't work. And I reiterate comments that Mr. Slater made earlier.
THE VIDEOGRAPHER: So would you like to go off the record right now, Counsel, then?
MR. SLATER: I don't understand why we're going off the record.
MR. BERNARDO: I don't either. I think if -- as long as my colleague can pull up the documents and share his screen so we can show Dr. Hecht what we're talking about, I think that will be more efficient.

Page 22

Is there a reason why we can't do that?
MR. BILY: You should be able to.
THE VIDEOGRAPHER: Okay.
MR. BERNARDO: There we go.
Q. And if you scroll through this document, this is a receipt of a document from ZHP. And if you take a look further and go through the document, let's turn to Section 3.2.
MR. BERNARDO: Which is on page 29, Josh.
MR. SCHOCH: Sure. This is the document.
MR. BERNARDO: Okay. All right.
Let's put up Tab 4, Exhibit 4.
(Exhibit Hecht-4, ZHP Product Development Report for Valsartan, Bates ZHP01710663 through 1710729, was received and marked for identification.)
MR. BERNARDO: Yes, yes. I'd like to mark this as Exhibit 4.
Q. Dr. Hecht, is this a document that you've seen before?
A. I believe so.
Q. Can you tell us your understanding of what this is?

Page 23

A. It's a product development report.
Q. From ZHP?
A. Yes.
Q. With respect to valsartan. Correct?
A. Yes.
Q. All right.
MR. BERNARDO: Let's go over to page 29 of this.
Q. And if you take a look at 3.2, "Huahai's Route," this is discussing the TEA process. And what I simply want to establish is that we agree, as described in this document, that the TEA process used triethylamine hydrochloride salt, TEA HCL, as the catalyst for the tetrazole formation, instead of [redacted]. Is that correct?
A. Correct.
Q. Okay. And it's used as a catalyst in order to avoid the usage of a metal-based catalyst -- sorry -- the TEA process, the tri [audio dropout] chloride was used as a catalyst, to avoid the usage of a metal-based catalyst, [redacted]. Is that correct?
A. Yes.
MR. SLATER: Objection.
You can answer.

Page 24

A. Yes.
Q. And that change eliminated the concern of removing any residual amount of metals during the production of valsartan, according to the company documents. Is that correct?
A. Yes.
Q. And the removal of metal; that would be a safety concern. Is that fair to say?
MR. SLATER: Objection.
You can answer.
A. A safety concern, maybe an environmental concern. I don't really know.
Q. Okay. But [redacted] has an unpleasant odor. Is that fair to say?
A. I've never smelled it.
Q. Okay. Would you agree that it could be harmful to employees during the manufacturing process?
MR. SLATER: Objection.
You can answer.
A. I really don't know.
Q. Okay. Isn't that something you'd want to know, to understand the nature or purpose of changes that were made that you're commenting on?
MR. SLATER: Objection.

Page 25

You can answer.
Argumentative.
A. I thought the problem with the [redacted] had to do with the potential environmental aspects of its disposal.
Q. Okay.
A. I don't really know anything about the smell.
Q. Fair. Thank you, Dr. Hecht.
MR. SLATER: Hey, Rich, just do me a favor. You're jumping in a little bit when he's still talking, so please just let him finish. Thank you.
MR. BERNARDO: Thanks for pointing that out, Adam, I'll try to be better.
MR. SLATER: I'm your friend, I'm here for you.
MR. BERNARDO: Same here, Adam.
MR. SLATER: I know that.
Q. And according to this document, the new catalyst, triethylamine hydrochloride salt, is also more cost-efficient than [redacted]. Is that correct?
MR. SLATER: Objection.
You can answer.

A. I haven't seen the numbers, but I would assume so, yes.
Q. And it says that in this document. Do you see, down where we're highlighting here?
A. Okay, I forgot that.
Q. And there's nothing wrong with a company adopting a change that improves a process, but also saves money. Is that fair?
MR. SLATER: Objection.
You can answer.
A. It sounds logical.
Q. Okay. Companies and scientists would do that all the time: They want to be more efficient and make a product, and reducing costs of making that product is an appropriate consideration. Is that fair?
MR. SLATER: Objection.
You can answer.
A. Well, we always try to be as efficient as possible in synthesis.
Q. Thank you.
A. So it sounds reasonable.
Q. Thank you. Let's talk about the TEA with quenching process.
And do you agree that ZHP filed its

original paper submission with the FDA for the TEA quenching process, in or about April of 2012?
A. Yes, that sounds right.
Q. Okay.
MR. SLATER: When you said the quenching process, Rich, did you mean with the sodium nitrite quenching process?
MR. BERNARDO: Yes.
MR. SLATER: Okay.
Q. And let's pull up company documentation here.
MR. BERNARDO: And I want to mark an amendment to the DMF dated 4/16 as exhibit -- what are we, five? Five.
(Exhibit Hecht-5, Amendment to Drug Master File dated April 16, 2012, Bates PRINSTON00079747 through 79755, was received and marked for identification.)
Q. Okay. Are you familiar with this document?
A. Yes.
Q. Okay. And what is it, Dr. Hecht?
A. This is the amendment where they're going to describe the change from [redacted] to triethylamine.

Q. Okay.
MR. BERNARDO: And let's take a look at page 4 of this document.
Q. And if you look at the bullets --
MR. BERNARDO: It's page 4 -- right.
Q. You'll see it talks about adding a quenching procedure after the tetrazole formation reaction in the crude valsartan, Step 4.
Do you see that? It's the third bullet down under three, Step 4?
A. Yeah.
MR. SLATER: What's the question?
MR. BERNARDO: I just want to ask if he sees there was a quenching procedure after the tetrazole reaction with the sodium nitrite solution that was added.
MR. SLATER: I object; I'm not sure that's what that's talking about.
Q. And it used a sodium nitrate and hydrochloric acid for that quenching, is that correct?
A. That's to quench the sodium, you said?
Q. Right. In the quenching procedure, after the tetrazole reaction. Correct?
A. Correct.

Q. Okay. If you go to page number 5, and there's a section called "Justification For -- Justification and Risk Assessment."
And in that section, you would agree that, according to the company, the sodium nitrate and hydrochloric acid solution was used to destroy the excess sodium azide used in the tetrazole formation reaction. Correct?
A. Yes.
Q. Okay. And that's because sodium azide can be explosive. Is that correct?
A. Correct.
Q. And it was also done to minimize the risk that sodium azide could be in the final product. Is that fair?
A. Yes.
Q. Okay. So that's another change that was done to enhance the safety of the process in the manufacturing environment. Is that fair?
MR. SLATER: Objection.
You can answer.
A. I'm not sure it was just to enhance safety. I imagine that's -- that's one consideration.
Q. That's a fair clarification, Dr. Hecht.

Page 30

One of the considerations was to enhance the safety of the process in the manufacturing environment with the change we just discussed. Is that fair?
A. Yes.
Q. Thank you. And then the TEA with quenching process also changed the molar ratio for the sodium azide used in the reaction. [redacted] And you see that in that bullet, under 3. Is that right?
A. Yes, yes.
Q. And that was done to decrease the formation of a potential impurity known as d-valsartan. Is that correct?
A. Yes.
Q. Okay. So the change with -- the change to TEA with quenching, one of the purposes was to reduce the amount of potential impurities. Is that fair?
MR. SLATER: Objection.
You can answer.
A. Yeah, I -- yes.
Q. Okay. If you go back to page 4 in Section 3 of the third bullet. The TEA with quenching, it also involved the replacement of [redacted] with [redacted] in the

Page 31

saponification process. Is that correct?
A. Yes.
Q. And that was what is described as a "nonfunctional replacement." Is that correct?
A. Yes.
Q. What's a nonfunctional replacement, what does that mean?
A. Well, I mean, the key thing there is the [redacted]. I'm not sure, actually, why they switched from [redacted] to [redacted]; I don't -- I don't remember. But it doesn't matter; it's the [redacted] that they need to saponify -- to convert the ester to the acid.
Q. Was that done --
A. Hydrolyze the ester.
Q. I'm sorry, say that again, I chopped over you?
A. They need the [redacted] for the hydrolysis of the ester.
Q. And was that a change that was intended to make the process more cost-efficient?
MR. SLATER: Objection.
You can answer.
A. I imagine so.
Q. And again, we discussed that there's

Page 32

nothing wrong with adopting a change that improves a process, but also makes it more cost-efficient?
MR. SLATER: Objection.
You can answer.
A. Well, I don't know about that. I mean, in this particular instance, it doesn't seem to make any difference. But, you know, every -- every process change that you make has to be considered individually, for its potential impacts on the overall process and on the overall product. So I don't know whether you can just generalize, you know. Every step -- every step is different.
Q. These changes, as part of the process, were provided to the FDA in documentation. Is that correct?
A. Yes.
Q. And in fact, we've looked at some of the documentation that was provided to FDA. Is that correct?
A. Yep.
Q. Okay. And FDA could respond to this documentation once it's received, or throughout the life of the product, if it has concerns. Is that fair?
A. Yes.

Page 33

MR. SLATER: Objection.
You can answer.
Q. Have you found any documentation, Dr. Hecht, showing that FDA responded to ZHP to raise concerns, prior to 2018, about the use of TEA?
A. No, I haven't seen that.
Q. Have you found any documentation showing FDA responded to ZHP to raise any concerns about the use of sodium nitrate -- nitrite and hydrochloric acid solution, prior to 2018?
A. No, I don't think there was anything before 2018.
Q. What about with respect to the use of any particular compounds or solvents or reagents? Have you seen any documentation showing that FDA responded to ZHP's submission to raise any concerns about that, prior to 2018?
A. No.
Q. Did FDA -- have you found any documentation showing that FDA responded to ZHP to raise concerns about the potential for nitrosamine formation, prior to 2018?
A. No, I haven't seen anything.
Q. Have you seen any documentation whatsoever, Dr. Hecht, indicating that FDA raised any

Page 34

concerns with respect to the process change we've just discussed?
MR. SLATER: Objection.
A. Yes.
Q. Prior to -- I'm sorry, Dr. Hecht. Prior to 2018?
A. No.
Q. Let's move over and talk about the last of the processes, the zinc chloride process.
MR. BERNARDO: And I want to mark as Exhibit 6 the amendment to the Drug Master File, if we can pull that up.
(Exhibit Hecht-6, Amendment to Drug Master File for Valsartan dated December 10, 2013, Bates PRINSTON00073102 through 73119, was received and marked for identification.)
Q. ZHP filed its original paper submission with the FDA for the zinc chloride process on December 10, 2013, just as it shows right there. Correct?
A. Yes.
Q. And have you seen this document before?
A. Yes.
Q. What is its purpose?
A. To describe the change in the process.

Page 35

Q. To whom are they describing the change in the process? Are they describing the change in the process to the FDA? Is that one of the purposes of this document?
A. I do not think so.
Q. Okay. It's an amendment to the Drug Master File. Correct?
A. Yes.
Q. And that gets submitted for a change to FDA. Correct?
A. Okay, I guess that's right.
Q. Okay. And you say you guess that's right, because you're -- fair to say, you're not really an expert in regulatory or FDA issues. Is that fair?
A. Yes, that's correct.
Q. Okay.
MR. BERNARDO: Let's take a look at Page Number 2 of 16.
Q. So the new process changed triethylamine hydrochloride salt to zinc chloride for the tetrazole formation. Is that correct?
A. Yes.
Q. And that change was to reduce -- and again, I'm sorry for my pronunciation, Dr. Hecht --

Page 36

racemization and reduce impurities, according to the document. Is that correct?
A. Yep.
Q. Okay. It also reduced an EHS concern, as it states there. Correct?
A. Reduced what?
Q. EHS? It's on the bottom left of the block that's highlighted?
MR. SLATER: You're asking, does it say that on the document?
MR. BERNARDO: I'm asking first, if it says that on the document, yes.
A. Oh.
Q. Would it help --
A. Yes, I guess it's environmental health and safety.
Q. Thank you. That was going to be my question. And you raised environmental concerns before, in response to another question. Correct?
A. Yes.
MR. SLATER: Objection.
You can answer.
Q. Because sometimes, manufacturers will make changes to their processes to address environmental concerns. Is that correct?

Page 37

A. If they're forced to, sure.
Q. If you turn to page 8 of 16 of the document, to the paragraph beginning "Therefore," which we will highlight for you.
Would you just please just read that paragraph into the record?
A. That's going to be hard to do.
MR. BERNARDO: Can you -- is there a way to blow this up a little bit. Thank you.
A. "Therefore, INT3/sodium azide zinc chloride with a quantity ratio of [redacted] [sic] -- I don't understand that -- "is preferred and adopted for a proposed process of tetrazole forming and the output quantity with wet basis from Step 4 is increased from [redacted] to [redacted] kilograms to [redacted] to [redacted] kilograms. The process validation has been conducted and confirmed the suitability of commercial production."
So in other words, they're getting better yield.
Q. Thank you. That was going to be my next question. Is it fair to say that a layperson's translation of this document -- of this paragraph you just read would be that using zinc chloride as a catalyst improved the conversion of the tetrazole

Page 38

formation reaction, and increased the crude process output? Is that a fair layperson summary?
A. Yes, it increased the yield of the tetrazole. But I don't know why -- I don't know why the word "conversion" is in there.
Q. Okay.
A. It increased the yield of the tetrazole formation from the precursor, in the reaction with sodium azide.
(Court Stenographer clarification.)
A. It increased the yield of the conversion to the tetrazole, in the reaction of the precursor with sodium azide, A-Z-I-D-E.
Q. Is it fair to characterize this as a change to optimize the manufacturing process?
A. Yes.
Q. Okay. And if you increase the yield or the crude output, is it fair to say that that would also therefore reduce the amount of non-valsartan substances from the process?
A. No. I wouldn't say that. I mean, I don't think you -- I don't think you can really describe it that way.
Q. Okay.
A. That's a little bit -- that's a little

Page 39

bit too broad.
Q. Fair.
A. You'd have to look at it in detail.
Q. Have you done that, have you looked at the change in the process in that level of detail?
A. No.
Q. Let's go back to page 2 of 16. Okay. Under the "Minor Changes" section.
So the zinc chloride process also changed the solvent for the tetrazole formation reaction from toluene to dimethylformamide, or DMF. Is that correct?
A. Yes.
Q. And that change was made to facilitate the synthesis. Is that correct?
A. Yes.
Q. And is it fair to say, that was also a change that would optimize the manufacturing process?
MR. SLATER: Objection.
You can answer.
A. I don't really know.
Q. Okay. The zinc chloride --
A. Presumably it did, but that's an assumption on my part.
Q. And if you don't know --

Page 40

A. The goal is to -- obviously, their goal is to optimize the process within the confines of regulatory aspects.
Q. And the zinc chloride process also changed the manufacturing process, so that the quenching occurred in the presence of an newly-added solvent -- which I'm not even going to try to pronounce -- MTBE. Is that correct?
MR. SLATER: Objection.
You can answer.
A. Yes.
Q. And the change to MTBE provided better solubility for the in situ intermediate, to avoid emulsification, disturbing the liquid delamination and separation process. Correct?
A. Right.
Q. So that change was intended to enhance the separation process. Fair?
A. Right.
Q. Again, a change intended to improve the overall manufacturing process?
A. Yep.
Q. Okay. That change also, to the hydrolysis process, decreased the formation of the impurity, d-valsartan.

Page 41

MR. BERNARDO: Do you want to put that back up again, Josh? Sorry about that. Are we in the right section? Okay.
Q. The change that we just talked about, Dr. Hecht, to the hydrolysis process also helped to decrease the formation of the impurity d-valsartan. Is that correct?
A. Correct.
Q. So that change to the process was intended to reduce the amount of potential impurities. Correct?
MR. SLATER: Objection.
You can answer.
A. Yes.
MR. BERNARDO: And you can take that down.
Q. Is it fair to say that, based on company documents, the change to the hydrolysis process also helped to minimize the unhydrolyzed valsartan methyl ester group, to provide a better overall yield of the reaction?
A. Yes.
Q. So now, we already -- I want to make sure we agree that this kind of change was submitted to FDA, the documentation we just looked at. You

Page 42

have no reason to dispute that. Is that correct?
A. Yes.
Q. Let me ask it a different way. Are you disputing -- I think we had some double negative in there, and I just want to make sure the record is clear. Are you disputing that -- withdrawn.
ZHP sent documentation of this change to FDA. Correct?
A. Yes.
Q. Thank you. And again, FDA could respond if it had concerns. Correct?
MR. SLATER: Objection.
You can answer.
A. I assume so.
Q. Okay.
A. I don't know, really.
Q. I didn't hear the last word. "I don't know," what?
A. I don't know really.
Q. Okay. Have you found any documentation showing FDA communicated any concerns about the use of DMF before 2018?
A. No.
MR. SLATER: Objection.
You can answer.

Page 43

Q. Before 2018, have you found any documentation showing FDA communicated concerns about ZHP's use of a sodium nitrite and hydrochloric acid solution?
MR. SLATER: Objection.
A. No, I haven't.
MR. SLATER: You're asking, Rich, about direct communications to ZHP, specific to the process. Right?
MR. BERNARDO: I'm asking him if he's found any documentations at all, any kind of communication whatsoever from FDA to ZHP, expressing concerns about the use of DMF, is what we talked about.
MR. SLATER: You're talking about specific to these processes. Right, prior to 2018?
Q. Do you understand my questions, Dr. Hecht?
MR. SLATER: Rich, why are you not answering me?
(Court Stenographer clarification.)
MR. SLATER: I'm not being contentious, I'm just trying to clarify that we're not talking about general communications that ZHP may have seen, as opposed to specific communications directed to

Page 44

these specific processes.
MR. BERNARDO: I'm not saying you're not trying to be helpful. I'm trying to make sure I can -- I'm communicating with Dr. Hecht --
MR. SLATER: Why can't you just answer my question, though? It's a yes or no, I don't understand.
BY MR. BERNARDO:
Q. Dr. Hecht, have you found any evidence of any communication between FDA and ZHP, expressing any concerns about ZHP's use of DMF prior to 2018?
MR. SLATER: Objection.
You can answer.
A. No, I haven't.
Q. Or its use of sodium nitrite and hydrochloric acid solution, prior to 2018?
A. I haven't seen that.
Q. Have you seen any documentation showing that FDA communicated, in any manner, concerns to ZHP, prior to 2019, about the potential for nitrosamine formation from the changes we've just described?
MR. SLATER: Objection.
A. Prior to 2019?
Q. '18.

Page 45

A. '18.
Q. Correct?
A. No.
Q. So there's no indication whatsoever that FDA had any concern about the process change that we discussed. Correct?
A. I have no idea. I haven't seen it.
Q. Thank you.
A. That's all I can say.
Q. That's all I'm asking you to say, Dr. Hecht. Thank you.
So we just we went through four different process changes that ZHP used in its manufacture of valsartan prior to 2018. I want to focus on one of them in particular, which is the last one we just discussed.
So just to sort of make sure we agree: ZHP used a zinc-chloride-catalyzed tetrazole formation reaction as part of its zinc chloride manufacturing process we just discussed. Correct?
A. Right.
Q. And that zinc-chloride-catalyzed tetrazole formation reaction involved sodium azide as a reagent, and used DMF as a solvent. Correct?
A. Yes.

Page 46

Q. Okay. And that's the step in the process that yielded dimethylamine. Correct?
MR. SLATER: Objection.
You can answer.
A. We don't really know that. The dimethylamine could have already been present in the dimethylformamide. I haven't seen anything in the documents that I have that indicates that ZHP ever looked into that possibility.
Q. So we don't still know exactly how the dimethylalamine [sic] occurred. I just want to make sure I'm understanding what you're saying. It could have occurred by degradation, or it could have occurred because it was already present in the DMF that was used. I just want to make sure that's what you just said?
MR. SLATER: Objection.
A. Dimethylamine, right.
Q. Sorry if I --
(Court Reporter Clarification.)
Q. Let me try that again, since we were talking over each other.
So we still don't know today whether or not the dimethylamine that was part of the nitrosamine formation process was already in the DMF,

Page 47

or whether it somehow degraded and -- from the DMF to form dimethylamine. Is that fair?
MR. SLATER: Objection.
You can answer.
A. The way you stated that, I mean, "somehow degraded"; that sounds likes it's, you know, a mysterious, unexpected process. The hydrolysis of DMF to dimethylamine is absolutely basic chemistry.
Q. Okay.
A. So I wouldn't say -- I wouldn't put it that way at all. So no, it's not correct.
Q. And well --
A. The way you -- the way you stated it.
Q. I appreciate that --
(Court Stenographer clarification.)
Q. I appreciate that qualification, Dr. Hecht. So let me ask the question in a different way.
So we still don't know today whether the dimethylamine that started or was part of the process that formed nitrosamines was present in DMF that was used as a solvent, or whether it degraded during the process, the DMF degraded during the process, to form dimethylamine. Is that fair?
MR. SLATER: Objection.

Page 48

You can answer.
A. From what I've seen, we don't know.
Q. Let me go back to where we were. So we're talking about the zinc-chloride-catalyzed tetrazole formation reaction, using sodium azide as a reagent.
ZHP was not the first to use a zinc-chloride-catalyzed tetrazole formation reaction using sodium azide as a reagent. Is that correct?
MR. SLATER: Objection to form.
A. I don't know. I assume that this chemistry was already known. I don't think they invented it.
Q. That was my question. ZHP didn't invent this reaction. Fair?
MR. SLATER: Objection.
You can answer.
A. I don't know, really.
Q. Okay.
A. That would be my assumption, but I don't really know.
Q. Okay. I believe, and correct me if I'm wrong, Dr. Hecht, that you've read the report of ZHP's expert, Dr. Xue? And it's spelled X-U-E, my understanding is, you pronounce it "sure," so if

Page 49

that's not --
A. Yeah, I read it.
Q. Okay.
MR. BERNARDO: Why don't we pull that up and mark that as an exhibit. And what are we up to?
MR. SCHOCH: Seven.
MR. BERNARDO: Seven.
(Exhibit Hecht-7, Expert Report of Fengtian Xue, Ph.D. dated December 22, 2022, No Bates, 107 Pages, was received and marked for identification.)
Q. And this is the report of Dr. Fengtian Xue, dated December 22, 2022. And this is the report that we just talked about that you read. Correct?
A. Yes.
Q. Okay.
MR. BERNARDO: If we could turn, Josh, to page 28. The middle of the first paragraph. Okay. In fact, the literature review.
Q. Bear with me one minute, I'm sorry, Dr. Hecht. I just want to point you to the right place. Okay.
And why don't you just take a minute to orient yourself to the topic about which Dr. Xue is talking? Are you able to read it in the size it's on

Page 50

the screen, Dr. Hecht?
A. Not when you highlight it like that, no.
MR. SLATER: It's harder to read.
A. It makes it harder.
Q. Got it. We'll just do that to point you to that?
A. Okay.
Q. Why don't you just take a minute to orient yourself to where you are on the report?
MR. SLATER: You want to him to read that sentence that says "in fact"?
THE WITNESS: I'm reading it.
A. Okay, yeah.
Q. Can you just read that sentence that says "in fact" into the record.
A. "In fact, a literature search related to the synthetic method to the production of tetrazoles using zinc chloride as a catalyst on SciFinder generated at least 28 reports, nine of which used DMF as a solvent for the tetrazole formation reaction. Importantly, none of these nine examples mentioned any side reaction caused by the decomposition of the DMF solvent."
Q. Do you have any reason to dispute that statement that you just read, or any part of it?

Page 51

A. This is very tricky of you. No, I don't. But I mean, there was no reason -- in those studies that he quotes, there would be no reason for anybody to even think about the partial decomposition or the hydrolysis of DMF. It's not an issue, so of course it wouldn't be reported.
Q. Okay. And Dr. Hecht, I just -- I'm here to ask --
A. I mean, this is -- this is amazing. I mean, why are you even asking this?
Q. Okay. And Dr. Hecht, first of all, I am troubled by your statement, and I just want to clarify --
MR. SLATER: That's argument, that you're troubled by the statement. Let's just ask the questions, okay?
Q. Dr. Hecht, I'm not here to trick you. I'm not here to do anything. I'm here to ask you questions. And I think I've been fair in asking you if you agree with them; and if you disagree with them, I'm going to ask you why you disagree.
So I want to make sure we keep this in that vein. I'm not here to trick you or be tricky.
A. Okay.
Q. So -- okay? I don't want to make this

Page 52

personal. Thank you.
A. Okay. No, it's not personal at all. It's just that this particular thing is irrelevant to the question, I think.
Q. Well, but let me --
A. It's true, I mean in his report, it's true they don't mention the decomposition, as he calls it, of the DMF solvent. That is -- that is true.
But it's also true that there's no reason why they would mention it, because it's not relevant to the chemistry that's being done there, presumably. I didn't look at every report.
Q. Fair. But Dr. Hecht, let's talk about that for a little bit. So if there are reports in the scientific literature using the exact same chemical formation or process, also using DMF, and it is your opinion that everybody would know that DMF would degrade during that process, wouldn't it be incumbent upon researchers either not to use it, or to report that possibility?
MR. SLATER: Objection.
You can answer. There's a lot in there.
A. Well, it's well-established in the literature that DMF, on heating, or even crude DMF,

Page 53

can contain small amounts of dimethylamine. That's well-established. In fact, DMF sometimes has a fishy odor due to the dimethylamine. So, you know, dimethylamine is a potential contaminant of DMF, that's well-established.
Q. When was it well-established, Dr. Hecht?
A. Oh, I don't remember the exact date, but it's well before 2018, that's for sure.
Q. And fair to say that part of your opinion isn't just that it was well-established, but that it was widely known. Correct?
A. I don't know how widely known it is.
Q. Well, that's my question. Did you -- let's talk about --
A. I mean, what do you mean by "widely known"?
Q. I'm asking you, since it was your opinion --
A. Yes.
Q. -- that any chemist, organic chemist looking at this should have known this, is it your opinion that any organic chemist in 2013 ought to have known the conditions under which DMF would degrade?
MR. SLATER: Objection.

Page 54

A. Any organic -- not exactly. I mean, my opinion -- I'll tell you what my opinion is. Okay? And then you can take it from there.

My opinion is that if they were using sodium nitrite to -- in this reaction, then they should have thought about the possibility that there might be some dimethylamine present that would get nitrosated under the conditions that they were doing the synthesis. That's what they should have thought.

Q. Why should they have thought of that?

A. Because nitrosamines are known powerful carcinogens, and they should have thought of the fact -- they should have thought of the possibility that, by using sodium nitrite at pH[redacted], which is perfect conditions for nitrosamine formation, they should have thought of the fact that their product might have been contaminated with dimethylnitrosamine. They should have thought of that, absolutely.

Q. Okay. But what we're talking about here is the first step of that; is the presence of dimethylamine in the process. Correct?

MR. SLATER: Objection.

You can answer.

A. And they should have thought of that.

Page 55

They should have thought, you know, if we use dimethylformamide, there could be some dimethylamine in there; we could form dimethylnitrosamine when we're dumping nitrite in this reaction to decompose the sodium azide at pH[redacted]

They should have thought of that. That's my opinion. That's my core opinion.

Q. And I understand that, and I thank you for clarifying that, Dr. Hecht. And I'd like to explore the core opinion, because I want to understand the process or steps you took to get to that.

And the first step would be: If somebody should have thought of something, is it fair to say that the first step would be: It has to be widely known. It has to be very knowable. It's not some esoteric fact. Is that correct?

MR. SLATER: Objection.

You can answer.

A. It is widely know that --

(Simultaneous speaking.)

(Court Stenographer clarification.)

THE WITNESS: Should I continue?

THE COURT REPORTER: Yes, please, Doctor.

Page 56

A. It is widely known that dimethylamine is easily nitrosated to form dimethylnitrosamine, using a sodium nitrite at pH[redacted] That is widely known. And it is widely known that dimethylamine is a potential contaminant in dimethylformamide, period.

Q. Thank you, Doctor. Again, I'm sorry --

A. Furthermore, they demonstrated that this was the case by forming dimethylnitrosamine in their product.

MR. BERNARDO: Ellen, would you just mind just reading the beginning of that? I apologize, something got cut off here. The beginning of his answer, I got the last part.

(Testimony read back.)

A. Dimethylnitrosamine.

Q. And again, thank you, let me just take back. Because you stated, Dr. Hecht, that this is your core opinion, and I appreciate that. And I really want to make sure I understand it, and what you did to get there.

And the first step I want to talk about is the presence of dimethylamine, because that's important that dimethylamine is part of this process that resulted in the formation of nitrosamines.

Do you agree with that?

Page 57

A. Yes.

MR. SLATER: Objection --

A. Yes --

MR. SLATER: One second, Doctor.

Objection to the form, compound, colloquy.

You can answer.

A. Dimethylamine is part of the problem, yes.

Q. Okay. So I really want to focus at this point just on the knowledge that DMF could degrade to form dimethylamine, or contains dimethylamine.

Do you understand where I'm trying to focus?

A. Yes.

Q. Okay. And you "said it 'is' widely known," or words to that effect.

A. Yes.

Q. What I want to understand is: It your opinion that in 2013, it was widely known that DMF could degrade under certain conditions to form dimethylamine, or have dimethylamine in it?

A. Yes.

Q. Okay. What is your basis for that? What steps did you take to determine what was known,

Page 58

and how widely it was known in 2013?
A. Well, I have various articles that I've looked at from the literature talking about, you know, the hydrolysis of DMF.
Q. And you cited to only two of them --
MR. SLATER: I'm sorry, had you finished, Dr. Hecht?
MR. BERNARDO: I'm sorry, I thought he was.
A. Yeah. So, you know, there's a number of different articles in the literature, and it's also described in certain texts. I've got all that -- I've got all that information; they should have known that.
Q. I understand you're saying they should have known, Dr. Hecht. And again, I want to understand why they should have known, and I want to understand the process.
I mean, it's fair to say, Dr. Hecht, it's your opinion they should have known that. And I understand that, and you can explain that to the jury. But I want the jury to understand how it is that you got there.
And I guess one thing you just said, and I want to unpackage that a bit, is it's in -- and I

Page 59

forget the word you used, several or some publications, and I think you said a text. Is that correct?
A. Yes.
MR. SLATER: Objection.
You can answer.
(Court Stenographer clarification.)
MR. SLATER: Doctor, what's happening is if you don't pause and I don't get the objection out and we talk at the same time, the court reporter is going to ask you to answer after I speak. So she just needs you to say "yes" again.
THE WITNESS: Are you talking to me?
MR. SLATER: Yep.
A. Yes.
Q. Okay. How many articles or publications are there or did you find that discuss the conditions under which DMF can degrade to form dimethylamine, such that it would be widely known?
MR. SLATER: Objection.
You can answer.
A. There are -- there's several that I found. I don't know the exact number. Some of them are like in textbooks. For example, WHO, that's the World Health Organization, states that DMF sold

Page 60

commercially contains trace amounts of methanol, water, formic acid, and dimethylamine. 1994.
Q. Okay. In that publication --
A. That's one example. So I mean, you know, this is not -- this is not something recent. I mean, DMF has been around a long time.
Q. Understood. And the document you just cited to is not in your -- referenced in your report or listed in the materials upon which you relied. Is that correct?
MR. SLATER: Objection.
A. It's not in my report, no.
Q. Okay. There were only two documents in your report upon which you relied or state that you relied, in connection with your opinions that deal with dimethylamine formation in DMF. Correct?
MR. SLATER: Rich, I believe that article is on the reliance list, just in case you didn't see it.
MR. BERNARDO: Okay, I'll take a look.
Q. Again, I want to go back to understand the steps that you took, Dr. Hecht.
So your opinion is that it's widely known. And is it fair to say -- and I don't want to put words in your mouth; I just want to make sure I

Page 61

can understand your opinion and we can talk about the basis for it. Is it fair to say it was your opinion -- it is your opinion that in 2013, any chemist who would be working with DMF should have known that DMF could degrade to form dimethylamine?
A. I don't know about "any chemist." You know, there are millions of chemists out there. Some of them aren't very smart.
Q. Okay. So then who should have known, in your opinion, about the degradation of DMF, and how did you go about --
A. The people at this company should have known. Absolutely, they should have known. They should have looked at it. Absolutely.
Q. Okay.
A. And I mean, you know, this is like textbook information. They should have thought of it.
Q. Okay.
A. I have no doubt about that.
Q. Okay. I understand. And I'm not trying to challenge your conviction to it, Dr. Hecht. I'm trying to understand, is it -- so maybe we can cut through this.
Did you go through any process

Page 62

whatsoever to determine that this should have been known to ZHP or any organic chemist using this, or is it just: This is Dr. Hecht's, you know, view of DMF?

A. No --

MR. SLATER: Objection --

One second, Doctor. One second.

Objection. Are you saying in addition to what he just told you, which is going to the scientific literature, or are you saying including that? What's the question?

MR. BERNARDO: I'm asking -- let me ask --

MR. SLATER: Because that question was a mischaracterization, and --

MR. BERNARDO: Withdrawn.

MR. SLATER: Wait, let me finish.

MR. BERNARDO: I'm withdrawing the question.

MR. SLATER: All right, but I just want to make it clear, because you're going to come back to this, so I want to make sure. And you ignored what you just asked him about for five or 10 minutes. So I don't think it's a reasonable question.

MR. BERNARDO: And that's why I've withdrawn it.

Page 63

Q. Dr. Hecht, in your report -- let's pull up a statement in your report. Hold on.

Actually, why don't -- sorry. I don't mean to delay this, we've been going for a little over hour. Why don't we just take a brief break, and we can pull up the report and we can walk through that.

THE VIDEOGRAPHER: Okay. Going off the record. The time is 9:21 a.m. Central Time. This is the end of Media Unit 1.

(A brief recess takes place.)

THE VIDEOGRAPHER: We are back on the record. The time is 9:33 a.m. Central Time. This is the beginning of Media Unit 2.

BY MR. BERNARDO:

Q. Dr. Hecht, I'd like to pull up your report from 2022 for a moment, and I'd like to focus on the paragraph that's at the bottom that is being highlighted here, right there.

And it says, "The readily available scientific knowledge and testing should have been applied to identify the NDMA and NDEA, even after the processes were adopted."

This is the sentence I want to focus on, Dr. Hecht. This -- presumably, you're talking about

Page 64

readily available scientific knowledge and testing "should have been apparent to any organic chemist involved in the development or assessment of these processes."

Did I read that right?

A. "Any organic chemist."

Q. Is that --

A. It should be apparent, yes, it should be apparent to -- so what are you asking, exactly?

Q. I simply was asking --

A. You're confusing me.

Q. -- to make sure we agree that I've read this correctly. That was all.

MR. SLATER: Doctor, all he's asking you is if he just read what your report says.

THE WITNESS: Yes.

Q. Okay. I just want to make sure we're on the same page.

So is it correct that there are several things that needed to have been known in order to utilize or apply the readily-available scientific knowledge? Correct?

MR. SLATER: Objection.

You can answer.

A. Several things? Sure.

Page 65

Q. Okay. So first, can we agree that one of the things that would have to have been known, such that it would be apparent to any organic chemist, is that DMF was present -- I'm sorry, is that dimethylamine was present or formed during the process.

Do you agree with that?

A. That it could be present, yes.

Q. Correct. Okay. So we do agree with that.

A. Yes.

Q. And you raise two, I think, distinct ways in which dimethylamine could be present in the process. One would be that ZHP used DMF that was contaminated with some amount of dimethylamine. Is that correct?

A. Yes.

Q. Okay. Did you do anything to investigate whether or not ZHP took steps to ensure that the -- that the DMF it was using did not contain dimethylamine?

A. Yeah, I looked through all the documents that I have, and I couldn't find anything that specifically said that they checked for the presence of dimethylamine in -- in the actual process, where

Page 66

they were doing the bulk synthesis of, you know, the valsartan.
Q. Okay. Let's talk about -- sorry, go on?
A. They did do one -- I did find an example of one kind of post hoc analysis that they did. Not for the process itself, but to, you know, to look into the possibility. I'd have to look again at that.
Q. Do you remember what was concluded from that analysis you're referring to?
A. Yes, I believe they checked the sample of DMF and -- for dimethylamine, and they didn't find any.
Q. Okay.
A. I think that's what they -- that's what they found. But that was -- that was not -- you know, that is the case, that's what it was. But that was not the -- that was not the DMF that was actually used in the bulk process, according to my understanding of what I read. That was like a post hoc analysis, you know, after they realized what was going on.
Then they said, well, let's look at the DMF, let's look at the DMF and see if we see any dimethylamine in it. But that wasn't necessarily the

Page 67

DMF that they actually used in the process. Anyhow, that's what I remember.
Q. Thank you. Let me talk about the documents with you for a minute. About how many documents would you say -- well, withdrawn.
Are the documents that you reviewed or considered in connection with forming your opinions those that are listed in your report, and supplemented by those that were provided to us a day or so ago? Is that the totality of documents that you reviewed?
A. I don't know what was provided to you. I have no idea.
Q. You don't know what was provided to us?
A. I have got eight binders in my office here. And so that's what I have. I don't know what you have.
Q. Understood. Let's talk about your eight binders, Dr. Hecht. Because I just -- I want to -- the purpose of this is, I'm not trying to be mysterious. I just want to understand what you've looked at, to see if you've looked at other documents than I may have in mind.
So you have eight binders of documents. And are those company documents pertaining to ZHP,

Page 68

those eight binders?
A. Some of them are company documents, yeah.
Q. Okay. Outside of those eight binders that include company documents of ZHP, are there any other documents, company documents of ZHP, that you have looked at?
A. Not company documents.
(Simultaneous speaking.)
MR. SLATER: Objection.
You can answer.
(Court Stenographer clarification.)
A. Not -- I haven't looked at any other company documents, other than the ones that I just mentioned.
MR. SLATER: Rich, just so that you know this, because I don't want you to be misled.
The binders were documents that -- it's some of the documents he had, we put into binders so he would have access to them in hard copy. It's not every single document.
I just want you to know that, just so that you don't have a disconnect with him, because there's no point to that.
MR. BERNARDO: I appreciate that, Adam,

Page 69

and that's what I want to explore and pin down, because I want to understand the scope of what Dr. Hecht looked at, so I can ask questions that take that into account.
MR. SLATER: Yeah, he's not a -- he's not a regular litigation, do-this-all-the-time expert. So when you use terms like "materials," you know, your reliance list and things; those aren't terms that he's using every day, so it's just -- I just want you to know, you just might want to just explain what you're looking at, or what you're asking about. Because I don't want you to be, you know --
MR. BERNARDO: I don't think we're near that point yet. So let me -- let's just keep going through this.
Q. So Dr. Hecht, here's what I'm trying to understand.
I want to understand the scope of or totality of company -- ZHP company documents that you personally reviewed, prior to forming your opinions in this case.
Do you understand what I'm trying to understand?
A. Yes.
Q. Okay. Thank you. So I think, based

Page 70

upon the discussion you and I just had, supplemented by what Mr. Slater told me, that some portion of those are in eight binders that you have with you today. Correct?

A. Yes.

Q. Could you estimate, outside of those eight binders, the number -- and I'm just looking for an estimate, like ten, a hundred, 10,000 -- the number of additional ZHP company documents that you reviewed?

MR. SLATER: Please don't give him a -- if you can give a reasonable estimate, you can do it, but please don't guess.

A. Could you repeat the question? I mean, I --

Q. Yes. Outside -- outside of those eight binders of documents?

A. Yes.

Q. I want to know approximately the number of ZHP company documents that you personally reviewed, prior to forming the opinions that you included in your reports in this case. Do you understand my question?

A. Right. I mean, I've seen some other documents online. I don't remember -- I don't

Page 71

remember the exact number.

Q. And I don't want an exact number. What I want to get a sense of is just a range. Are we talking about fewer than a hundred?

MR. SLATER: Objection.

A. It depends how you define "document."

Q. I'm defining it as --

A. What is the definition of "document"?

Q. I'm defining a document as a ZHP company document; a document kind of like what we were looking at before, that appears to have been authored by or written by ZHP, a ZHP company document.

Does that help you answer the question?

A. Yeah. So what was the question again?

Q. The question was: Outside of the binders that we're talking about -- and I'm sorry, let me withdraw that question.

The eight binders you have, I think you may have answered this, and I've forgotten already. Are those just ZHP company documents --

A. No.

Q. Or are there other kinds of materials?

A. No, there are other materials, too.

Q. Could you estimate the percentage, a quarter, half, 75 percent of the eight binders that

Page 72

you reviewed, that are with you that are company documents, roughly?

A. Well, not all the binders are purely company documents. Okay? Some of them are like a mixture. But probably half of them have --

Q. Okay. That's about --

A. -- company-related material in them.

Q. Got it. So about four binders, roughly? And again, I'm really looking to get rough --

A. Very rough.

Q. Okay. Outside of those four binders of company documents, about how many others? Fewer than a hundred, or more than a hundred?

MR. SLATER: Objection.

Q. Of company documents?

MR. SLATER: Objection.

A. Probably fewer than a hundred.

Q. Okay, that's all I'm looking for. So the four binders, plus fewer than a hundred.

Do you have any understanding of the number of company documents that were provided in this litigation by ZHP?

A. I have no idea.

Q. How did you come to receive those documents, the company documents that you looked at

Page 73

in forming your opinions?

A. The law firm provided them to me.

Q. Did you ask for particular documents, did you take what they sent you, something else?

A. I don't really remember. I don't think I asked specifically for documents, but I don't really remember.

Q. Fair. So you basically looked at the documents that plaintiff's counsel selected and provided for you. Is that a fair statement?

A. Yes.

Q. As you were going through those -- withdrawn.

I think you know that ZHP is a Chinese company, and that many of the documents are in Chinese. Is that fair?

MR. SLATER: Objection.

You can answer.

A. Sure. But the ones I have have, you know, translations. They have English translations.

Q. Because you don't speak Chinese. Fair?

A. That's correct, yeah.

Q. Okay. And Dr. Xue speaks -- ZHP's expert speaks Chinese. Is that correct?

A. Yep.

Page 74

Q. And in his report, he cites to other documents that he states -- and I'm not asking you to agree or disagree -- but that he states support his opinion, that are in Chinese. Correct?
A. Yes. Yeah.
Q. Fair to say, you didn't look at those documents, correct, because you wouldn't be able to understand them?
A. I didn't read them, no, because I don't read Chinese.
Q. Right. So you mentioned that post hoc, I think that was your word, ZHP took steps to determine that there was no dimethylamine in the DMF it used. And it determined, in that batch that it looked at post-hoc, that there was none. Correct?
A. That's how I recall it.
Q. Is it fair to say that you have no knowledge, one way or the other, as to whether or not ZHP evaluated the DMF that was used in their valsartan in 2013 to ensure that there was no dimethylamine?
MR. SLATER: Objection.
You can answer.
A. I haven't seen it.
Q. But we just established you've not seen

Page 75

all of the documents. Correct? Because some of them --
MR. SLATER: Objection. Objection. This is argumentative. I mean, I mean -- there's -- and the question -- the foundation is improper; it's a misleading, mischaracterizing question. I'm happy to explain to you why, if you wanted to do it without Dr. Hecht. But --
MR. BERNARDO: No need to explain. I fully understand your objection, Adam, and I will take it into account in my questions, and you can address them later.
Q. So Dr. Hecht, I just want -- again, for purposes of understanding the basis of your opinions, I want to understand what you've looked at.
Because don't you think it's important for the jury to understand if you've seen, you know, all the materials, a portion of the materials, a few selected materials? Don't you think that would be important, for the jury to understand your opinions?
MR. SLATER: Objection to this question. I don't think he's here to be an expert on what the jury needs to -- would want to see or not.
You can answer.
A. Right, I agree with Adam.

Page 76

Q. So you don't think it really matters at all as to whether you've seen the complete record, or only a portion of the record?
A. I don't know. I mean, you know, I've -- I've seen enough to convince me that they didn't know what they were doing.
Q. Okay. All right. Then let me just -- I think you'll agree with me on this, and then we can move on, but let me just make sure. As you sit here --
A. I mean, they were totally oblivious. You know -- okay, go ahead, sorry.
Q. That's okay. As you sit here today, do you agree you have no knowledge whatsoever as to whether or not ZHP took steps in 2013 to ensure that their DMF did not contain dimethylamine?
MR. SLATER: One second. One second, Doctor. Don't answer yet.
I object. And I just want to say: Counsel, if there are documents that you think address this question specifically, and you're representing it happened, I'd like to see them, because they've never been produced.
Q. Can you answer the question? Can you answer the question?

Page 77

MR. SLATER: Wait, let me just finish.
Because you're talking about your expert looking at documents in Chinese, which I don't even know if we have them, I don't know if we have translated versions. And I'm starting to be concerned that you're suggesting something that you and I know didn't happen.
But you can go ahead.
MR. BERNARDO: Court Reporter, would you repeat the question?
(The testimony is read back.)
A. I don't know if they did that or not.
Q. Okay. Thank you.
A. I do not.
Q. Let's move to the second piece. So again, dimethylamine can be in DMF in, I think, two ways we just discussed. One, it could be in there already, and we just talked about that. Correct?
A. Yes.
Q. Okay. And then the second is, it could degrade under certain conditions to form dimethylamine. Correct?
A. Yes.
Q. Okay. I want to talk about the second piece only, because I've moved past the first. So I

Page 78

want to talk about knowledge that, under certain conditions, dimethylamine could degrade -- I'm sorry, withdrawn. I want to talk about -- that's the problem with the -- I want to talk about the knowledge that was available, in your opinion, regarding that, as to the degradation of DMF to form dimethylamine.

Do you understand the very narrow question that I'm going to be exploring with you?

A. Yes.

Q. Okay. I want to go back to --

MR. BERNARDO: If you could pull up, Josh, Dr. Hecht's statement.

Q. And I understand that this statement doesn't say what I just said. But a piece of -- but what I just said is a piece of this statement.

Would you agree, in order for ZHP -- if there was no DMF that was in -- withdrawn. I need more coffee.

If there was no dimethylamine in the DMF that they used, they would have to know that dimethylamine could form from DMF, in order to start the process that resulted in nitrosamines. Is that fair?

MR. SLATER: Objection.

Page 79

You can answer.

A. Yes.

Q. Okay. And again, I want to be very clear. These are not the words in there, but I want to see if this is your opinion.

Is it your opinion that it should have been apparent, to any organic chemist involved in the development or assessment of this process, that DMF could degrade under certain conditions, back in 2013? Is that your opinion?

A. Yes.

Q. Thank you.

MR. BERNARDO: So you can remove that.

Q. So I want to --

A. Especially as it relates to this process.

Q. Sure. So I want to go back to where we were before. And I don't think we need to put up these articles, and I understand your views on that statement.

But you don't dispute that there are articles in the scientific literature before 2013 that have a similar process that formed the tetrazole ring and utilized DMF. Correct?

MR. SLATER: Objection.

Page 80

You can answer.

A. No, I don't dispute that.

Q. Okay. And again, I'm not asking you, because I know you've not looked at them, but do you have any reason to dispute that none of those papers mention the degradation of the DMF into dimethylamine -- or to form dimethylamine?

MR. SLATER: Objection.

You can answer.

A. They wouldn't mention it, because it's not relevant. All right? I mean, the trace amount of dimethylamine that's present in the DMF only becomes relevant because they're dumping sodium nitrite into the reaction.

If it's another kind of reaction where, you know, they're using DMF as a solvent, and, you know, there's a certain amount of dimethylamine formed, it's not relevant to the product, so it wouldn't even be mentioned.

Q. Okay.

MR. BERNARDO: I want to take a look, Josh, if you can pull up -- hold on the patent, what number is that?

MR. SCHOCH: Exhibit 8.

Q. Okay. I want to pull up and mark as

Page 81

Exhibit 8 a March 26, 1996 United States patent.

Do you see what's on the screen, Doctor?

(Exhibit Hecht-8, United States Patent 5,502,191, Issued March 26, 1996, was received and marked for identification.)

A. Yes.

Q. Okay. I don't -- have you seen this document before? I'm guessing not, but...

A. I don't know.

MR. SLATER: What exhibit number was that, I'm sorry?

MR. BERNARDO: Eight, Adam.

MR. SLATER: Thank you.

MR. BERNARDO: Sure.

MR. SLATER: We're starting to get up in big numbers, so...

MR. BERNARDO: I know. When we hit double digits, we're going to be in trouble.

Q. Have they fixed your Exhibit Share yet, Dr. Hecht? Because I'd like you to take a moment and look at this document, and then I want to ask you a couple of questions about it.

A. Okay.

Q. Have they fixed your Exhibit Share so that you can do that?

Page 82

A. Well, I can see it on the Zoom screen.
Q. Oh, okay. It's longer than just what's on the Zoom screen; that's why I just wanted to do it. Well, why don't I ask you the questions and you can tell me if you feel like you need to see more about it. Right?
So this is a patent from, you could see on its face, March 26, 1996. Correct?
A. Yes.
Q. And it talks about a method -- I'm sorry, if you look at the abstract, a method for making five-substituted -- slower -- a method for making five-substituted tetrazoles of Formula I. And it shows you the tetrazole ring. Correct?
A. Right.
Q. Thank you. And if you -- I'll --
MR. BERNARDO: Josh, if you just want to go through the next two pages and give Dr. Hecht a moment to take a look at those.
Q. And it goes through the background and the summary of invention. And I'm going to give you my question on page 4, and you can tell us if you need to take a look at this more. I don't think you will, based upon your prior testimony, but I want to see.

Page 83

And if you look, part of the background gives a description of some examples of the use. And here's Example 1. Okay? Do you see that?
A. Yeah.
Q. And can you --
MR. SLATER: And Rich, just for the record, is that pink highlighting on the document as it will be submitted as an exhibit?
MR. BERNARDO: Yes.
MR. SLATER: Okay.
Q. And I just want to focus you on the language in the pink highlighted.
A. Yep.
Q. If you'd just take a minute and take a look at that.
A. Okay.
Q. Okay? And you see it adds some sodium azide, according to what's described there. Correct?
A. Yeah.
Q. And then the reaction mixture with DMF, zinc chloride, and sodium azide is heated for 36 hours. Do you see that?
A. Yes.
Q. Okay. And then it's cooled off and acidified with hydraulic -- I'm sorry, hydrochloric

Page 84

acid. Do you see that?
A. Uh-hum.
Q. Okay. So this is a patent that is describing, in 1996, a process that is very similar to ZHP's zinc chloride process. Is that fair?
MR. SLATER: Objection.
You can answer.
A. It is.
Q. Thank you. And I will represent to you, just because we're having document issues: Nowhere in this document does it mention that DMF can degrade. Do you have any reason to dispute that?
MR. SLATER: Objection, that's really not a reasonable question to ask him. It's a long document that he hasn't had a chance to read. How would he have any basis to dispute it when he hasn't read the document?
MR. BERNARDO: Fair enough.
Q. I will represent --
MR. SLATER: If you want to represent it and ask him --
MR. BERNARDO: I'm going to represent --
MR. SLATER -- assuming that you're correct -- let me finish. If you want to represent it and ask him, assuming that you're correct, and

Page 85

then you want to ask a question based on that, I wouldn't object to that.
MR. BERNARDO: That's what I was about to do, Adam.
MR. SLATER: I'm here for you.
BY MR. BERNARDO:
Q. Dr. Hecht, I will represent to you that nowhere in this document does it mention that DMF might degrade. And before you said, in these scientific publications, they wouldn't need to, because it's the -- I think you used the dumping of acid. But this process similarly uses acid as -- after it has cooled. Is that correct?
MR. SLATER: Objection.
One second.
That mischaracterizes the prior testimony.
Go ahead.
A. What I said before was that there was no reason to mention it because you weren't adding sodium nitrite. You know, there was no reason to be concerned about a small amount of dimethylamine that might have formed from the DMF. There was -- you know, there was no reason to even think about that.
Q. Okay. Is that your testimony with

Page 86

respect to this as well, just so we can understand that?
A. No --
MR. SLATER: Objection.
Stop, stop, Doctor. Doctor, one second, just let me just get my objection in.
Objection, because this is, as well as this patent, that he obviously hasn't read. So, I'm just -- I just want to make it clear what the "this" is.
Q. So Dr. Hecht, based on the description that is highlighted in pink, which is similar to the process that ZHP used, wouldn't you expect that if the degradation of DMF to form dimethylamine was widely known, that that would be referenced in here?
MR. SLATER: Objection.
You can answer.
A. No. Because this patent, this process, doesn't say anything about adding sodium nitrite to decompose the sodium azide. It doesn't go into that.
Q. What's the effect of --
A. At least not what you're showing me.
Q. Sure. What would be the effect of adding the sodium nitrite that would cause the degradation?

Page 87

MR. SLATER: Objection, that's a -- there's no foundation to that question.
A. I don't get the question.
MR. SLATER: It doesn't makes sense.
A. I don't get your question.
Q. Sure. Dr. Hecht, explain to me the circumstances of the zinc chloride process that set the stage for the decomposition of DMF to form dimethylamine?
A. They had added sodium nitrite to decompose the excess sodium azide. The sodium azide on that scale is an explosion risk, so they had to add sodium nitrite to get rid of the sodium azide. Sodium nitrite will react with sodium azide to decompose it. So that's why they add the sodium nitrite.
Q. And what effect did the --
A. But they don't talk about that here.
Q. What effect did the addition of the sodium nitrite have on the degradation of DMF to form dimethylamine?
MR. SLATER: Objection.
You can answer.
A. None. I mean, the dimethylamine was already there. The dimethylamine formed during the

Page 88

heating process of the dimethylformamide.
So the dimethylamine was already present in the reaction mixture. And then when they added the sodium nitrite without extracting product out first, then the dimethylnitrosamine formed and contaminated the product. They could have avoided the whole thing by just extracting out the product first.
Q. So it's your opinion that the point at which the dimethylamine formed was during the heating process? I just want to make sure I'm understanding your testimony. I don't want to put words in your mouth?
A. No, I don't know. It could have been present in the DMF to begin with. I haven't seen anything that says that they tested their DMF to ensure that it was free of dimethylamine.
Q. Okay.
A. I didn't see that.
Q. Understood.
A. Maybe it's in some of the other documents, I don't know.
Q. Okay. And I don't want to go back to that, and I appreciate your making that qualification, because I do want to make sure your

Page 89

testimony is very clear.
So again, I want to compartmentalize this so I can understand what you're saying.
So we're going to assume, for purposes of these questions, there was no dimethylamine in the DMF at the time it was used. What I want to talk about is, if the dimethylamine was formed during the degradation of DMF, is it your testimony that that happened at the point at which the -- well, you tell me: At what point in the process did that happen?
A. Well, if it wasn't there to begin with, then it happened during the [redacted] hours that they heat the mixture to the tetrazole formation reaction. It happened during that heating process.
Q. Great. Thank you very much.
MR. BERNARDO: You can take that down.
A. I am sure of that.
Q. So I want to go back, Dr. Hecht, to --
MR. BERNARDO: Can you put his report back up.
MR. SCHOCH: Uh-hum.
MR. BERNARDO: Yes, please.
Q. I want to go back to this sentence. So, "it should have been apparent to any organic chemist."

Page 90

Should it have been apparent to any organic chemist in 2013 that DMF, when heated to its boiling point, would degrade to form dimethylamine, in your opinion?
MR. SLATER: Are you asking any organic chemist -- okay, go ahead. Are you saying any organic chemist --
(Simultaneous speaking.)
A. I don't know about any organic chemist.
(Court Stenographer clarification.)
MR. SLATER: Go ahead, Doctor.
A. It should have been apparent.
(Simultaneous speaking.)
Q. And again --
A. Let me --
MR. SLATER: Rich, Rich. Objection to form --
(Simultaneous speaking.)
A. I don't know about any --
(Court Reporter Clarification.)
THE WITNESS: Yes.
Q. I want to go back, and I think you said --
MR. SLATER: You've got to stop for a second. He's still --

Page 91

MR. BERNARDO: No, I don't, because my question was very clear --
MR. SLATER: I haven't even gotten my objection in yet.
MR. BERNARDO: Adam, I'm using his language.
MR. SLATER: Can I speak?
(Simultaneous speaking.)
MR. BERNARDO: -- fairly long. And you've been doing that throughout the deposition.
MR. SLATER: Can I object? Can I place my objection or not? It was a simple question for you, when you say "any organic chemist," because you've been over this with him now four or five times already in the deposition, I was going to ask you: Are you talking about any organic chemist that was involved in the development and the oversight of the process, or are you talking about the organic chemist that's, you know, working in a high school in Kentucky right now, teaching 10th grade chemistry?
Because he's already clarified that opinion multiple times already, so I'm just asking: Are you asking a different question?
MR. BERNARDO: I'm not asking a different question. I think it's been clear the

Page 92

question I'm asking, but it's up to Dr. Hecht to tell me if he's not --
MR. SLATER: I don't think it is clear; that's why I'm objecting.
BY MR. BERNARDO:
Q. Dr. Hecht, let me rephrase the question.
In 2013, should it have been clear -- I'm sorry. In 2013, should it have been apparent to any organic chemist involved in the development or assessment of these processes that DMF could degrade to form dimethylamine at its boiling point?
A. Yes.
Q. Thank you.
What steps did you take to determine that in 2013, it should have been apparent to any organic chemist involved?
MR. SLATER: All right, let me just -- stop for a second, Doctor.
You literally asked this question like an hour and a half ago, and he talked about the literature and he went through this.
Is this a new question, or are you saying in addition to what he's already said? You're going over old ground already.
MR. BERNARDO: I'm not going over old

Page 93

ground, Adam, and I would appreciate it if you wouldn't feed Dr. Hecht --
MR. SLATER: I'm not feeding him anything --
(Simultaneous speaking.)
MR. SLATER: You've literally -- well, look, you can't just keep going over the same -- you've asked that question already. So I'm asking, is it a new question or the same question? Because I object to the same question being asked over and over. That's not a reasonable use of the time.
Q. Dr. Hecht, would you please answer my question?
MR. BERNARDO: And these are my seven hours and I have a limit of seven hours, and it's not up to you to determine what's a reasonable use of his time.
A. Could you repeat the question?
Q. Yes. What was the process that you went through -- now that we've established what your opinion is, which it should have been apparent to any organic chemist involved in the development or assessment of these processes, that DMF would degrade at its boiling point; what was the process you went through to determine what should or should not have

Page 94

been apparent to any organic chemist involved in the development or assessment of the process?
MR. SLATER: I object, asked and answered.
You can answer again.
A. I looked in the literature to see whether, you know, the contamination of DMF with dimethylamine or the formation of dimethylamine from DMF was, you know -- was reported. I mean, there's no doubt that DMF can hydrolyze to dimethylamine when you heat it for [redacted] hours at [redacted] degrees, or whatever it was. I mean, that's like basic organic chemist -- chemistry. Yeah, I mean, I think, quote, any organic chemist would know that.
But there's also a fair amount of literature on just contamination of DMF with dimethylamine. I think I noted before that sometimes it has a fishy odor, due to the dimethylamine. But there's -- you know, there's published literature. I mean, you know, I have a paragraph here from Fields, you know, "methods for removing the FMOC group."
(Court Reporter Clarification.)
A. FMOC, F-M-O-C. In Methods in Molecular Biology, Volume XXXV, Peptide Synthesis Protocols, published in 1994 by Humana Press in Totowa,

Page 95

New Jersey.
And what that -- within that volume -- within that volume on page 22, it says that "amine impurities that could possibly remove the FMOC group include dimethylamine found in DMF," and then it references Number 47. I'm not sure what 47 was.
But anyhow, you know, this is like -- this is not something new. I mean, DMF has been around a long time, and this is -- this is not new, that there might be some dimethylamine in the DMF, or the dimethylamine could form when you heat DMF at [redacted] degrees for [redacted] hours.
Q. Dr. Hecht, was the example you just gave me an example -- you used the word "found," I don't have the article you're looking at. Was that an example where DMF --
MR. SLATER: It's on the reliance list, the supplemental list.
Q. Dr. Hecht, I don't have the article in front of me that you're looking at. You just used the word "found." Was that an article that discusses the presence of dimethylamine in DMF, or is that an article that discusses the degradation at its boiling point?
A. No, the presence.

Page 96

Q. Okay. Again, I really want to try and be efficient here, Dr. Hecht. I don't want to ask any more questions, and I'm not intending to ask you any more questions, about the presence of dimethylamine in DMF. I really want to focus this discussion on the knowledge, or what should or should not have been known in 2013, by any organic chemist involved in the development of these processes. That's really what I want to focus on, Dr. Hecht. Do you understand my --
A. Okay, sure.
Q. Okay. And I understand your testimony, and I'm just really trying to make sure I can understand how you got there. That's really what I'm trying to do.
And you mentioned that it's cited in some literature that you found. Does the fact that a concept is cited in literature mean that it should have been known to any organic chemist in a process that involves that constituent or process, in your opinion? Does the mere citation in the literature to something?
A. Well, yes. It's my opinion that in this particular case, they definitely should have taken this into account; that's my opinion. You can't

Page 97

change it.
Q. And Dr. Hecht, I wouldn't begin to try to, nor is it my goal to change your opinion at all. That's not what this process is about. I respect your opinion, you're entitled to your opinion; I just want to understand the steps you took to get there. That's really the purpose. So this is not trying to change your opinion.
So Dr. Hecht, you would agree that there are -- I couldn't even begin to estimate; probably tens of thousands, if not hundreds of thousands, of publications in the world's scientific literature. Is that a fair statement, generally?
A. Sure.
Q. Okay. And certainly, an organic chemist at a company couldn't be expected to know everything that's in every one of those pieces of literature. Is that a fair statement?
A. Yes, that's correct.
Q. And in fact, you're a very well-respected scientist, and you don't certainly purport to know everything that's in the world's literature. Is that fair?
A. Yeah, I guess.
Q. Okay. You'll give me that one.

Page 98

So what I'm trying to understand -- and let me just, let me give you an example. So the -- withdrawn.

What I'm trying to understand is, how does a piece of information go from being referenced in an article or several articles, to being something that should be widely known by any organic chemist in the development or assessment of a process? How does -- how do you distinguish between any fact in the scientific literature, and one that is so well-established that any organic chemist involved in the development or assessment of these processes should know it? What was your process of getting there?

A. The answer is awareness. Okay? If you're developing a specific process, it's your responsibility to be aware of all aspects of that process. Not only just that, "Oh, this process works, because it gives us a high yield and it's less expensive, so this is going to give us a great yield of our product." No.

You have to know all possible aspects. You have to consider the possible hazards that are involved with your -- with your process, and you have to consider the possible costs that are involved with

Page 99

your process. You have to consider the environmental impact of the process that you're using. You have to consider whether the drug that you're making, if you're making a drug, is going to have toxicity.

It all has to do with the awareness of the particular part of organic chemistry that you're working in. You can't be -- you can't know everything, but you have to be aware of the specific aspects of the process, and its possible consequences, that relate to this particular reaction conditions that you're using. It's awareness.

Q. Awareness of everything that's in the scientific literature?

A. No.

MR. SLATER: Objection.

One second, Doctor --

A. Not everything.

MR. SLATER: Stop. One second.

A. You can't be -- it's impossible to be aware of everything. But you do -- it is your responsibility to be aware of the aspects that relate to your particular process. That is absolutely basic.

Q. So, Dr. Hecht, you wouldn't dispute that the FDA has some of the world's leading chemists and

Page 100

scientists that it utilizes in evaluating pharmaceuticals that we all consume. Is that fair?

MR. SLATER: Objection. Objection. Lack of foundation.

MR. BERNARDO: I'm asking the -- I'm asking if he knows it.

MR. SLATER: Well, I object to the question, the foundation and the way the question was asked. He can answer it.

A. I don't know.

(Court Stenographer clarification.)

MR. SLATER: He said, "I don't know."

A. I don't know whether the FDA has some of the world's greatest scientists.

Q. Okay. Do you know if the FDA scientists were aware or not aware that DMF could degrade at the boiling point?

MR. SLATER: Objection to form.

A. I do not know.

Q. Okay. Let me just change --

MR. SLATER: You know, Rich --

Q. Moving on. So Doctor -- Dr. Hecht, the valsartan, ZHP's valsartan manufacturing process is a multistep process. We can agree on that. Right?

MR. SLATER: Which process are we

Page 101

talking about?

MR. BERNARDO: Sorry. The zinc chloride process.

A. Could you repeat the question, please?

Q. Sure. It's just a foundational question. I just want to -- I think we agree that there are many steps in the process of making valsartan. Whether it's the zinc chloride process or the TEA with quenching process, it's a multistep process. Is that fair?

A. Yes.

Q. Okay. I'm just trying to make sure I understand your opinions as to which step really matters here, for purposes of discussion. I'll give where I'm going, just to make sure that -- I think I know what your opinion is, but I want to make sure.

And you believe that nitrosamines formed during the crude valsartan step. Is that correct?

A. What do you mean by "the crude valsartan step"?

Q. The -- do you want me to go back to our first -- Step 4, basically, that we discussed earlier?

A. I don't remember --

MR. SLATER: Do you want to put back up.

Page 102

A. What you mean by "Step 4."
Q. Let me do it this way.
A. It forms when they dump in the nitrate.
Q. Okay. Does it -- let me see if I can approach it this way.
Does it form at any other step of the manufacturing process, in your opinion?
A. Not before the nitrite.
Q. Thank you. That's all I'm just trying to --
A. I don't knowing about after the nitrate.
Q. Fair enough. And is it your opinion that NDMA formed during that part of the process -- only NDMA formed during that part of the zinc chloride process?
MR. SLATER: Objection. I'm not sure I understand the question.
A. I didn't get it either.
Q. Sure. Do you believe that NDMA formed during any process, other than the point we just described in the zinc chloride process?
MR. SLATER: Objection. When you say "the process," do you mean "step"? Isn't that the question you just asked him?
Q. Dr. Hecht, can you answer?

Page 103

A. The NDMA -- the NDMA forms when you add the nitrite, add the sodium nitrite.
Q. Okay. Do you have an opinion as to whether NDEA forms at that point?
A. The NDEA was from the triethylamine process.
Q. And that's what I'm trying to establish, Dr. Hecht --
A. But that's a different, that's a different process.
Q. Exactly. That's all I'm trying to establish. I just want to make sure that my understanding of your opinion is correct; which is that NDMA only forms during the zinc chloride process, and that NDEA forms only during the TEA with quenching process?
MR. SLATER: Objection.
Q. I believe that's what you're saying, but I just want to confirm that, and if it's not, I want to understand?
A. Yes, I believe that's correct.
Q. Okay. Thank you.
(Court Reporter Clarification.)
Q. Dr. Hecht, one of your opinions -- I want to move on to the -- I want to move out of DMF

Page 104

degradation, and on to the risk assessment process.
Are you with me?
A. Yeah.
Q. Great. One of your opinions is that ZHP failed to perform what you describe as a -- and I think the word you use is "straightforward" risk assessment.
Do you agree with that, or do you want to see your report?
A. Yes.
Q. Okay. Now, you are not saying that ZHP failed to conduct any risk assessment. Correct?
A. No, I'm referring to specifically the possibility of nitrosamine formation during their process.
Q. Okay. So you would agree that ZHP did, in fact, conduct a risk assessment for its TEA-with-quenching process. Correct?
A. You lost me.
Q. Sure. Did ZHP conduct a risk assessment or not for its TEA-with-quenching process?
A. With respect to what?
Q. Any risk assessment whatsoever, of that process?
A. Oh, I don't know risk assessment.

Page 105

That's a big word. You know, they have to -- they have to consider many factors before they initiate a process on that scale. There could be any number of factors. So I don't know if they considered -- you know, I don't know if they carried out a risk assessment for various different things. I have no idea.
Q. I want to make sure my question is clear, because I'm not sure, based on your answer, it is, so let me just try this again. Okay?
Before changing -- we talked about the four processes. Right? And the last two processes, we went through changes that the company made, and the documentation about those changes that they submitted to FDA. Right?
A. Yes.
Q. Okay. Before they made or proposed to make those changes, do you agree -- let's talk about the TEA quenching, the changes they made for the TEA quenching process. Do you agree or not that they conducted a risk assessment with respect to those changes?
A. I don't know, because a risk assessment -- you know, what do you mean by "risk assessment"? That's a huge word.

Page 106

Q. Can we pull up your report? Just a minute, we're going to just pull up your report, Doctor. Because I just want to make sure we're...
MR. BERNARDO: It's on page 2. There you go, Josh.
A. Okay.
Q. Let's put it in your words.
So "ZHP failed to perform a straightforward assessment of the chemistry."
Do you see that?
A. Yes.
Q. Okay. Is it your testimony that they performed no assessment, or you just disagree with the thoroughness or detail of the assessment? That's what I'm trying to understand?
A. I don't know if they -- I have no idea whether they did an assessment or not. I mean, I can only go on what's reported. Maybe they did an assessment and they -- and they decided, you know, there's no problem, so let's go forward, and it was never recorded. I don't know. Maybe they did an assessment, maybe they didn't. I have no idea.
Q. Okay. So -- so your characterization of the assessment as not being straightforward; you don't know one way or the other whether they did any

Page 107

assessment. That's your --
MR. SLATER: Objection, that's not what he said.
A. No, all I know is --
(Simultaneous speaking.)
Q. I withdraw -- I withdraw my question.
MR. SLATER: Okay.
Q. Why don't we -- did you ask to see, Dr. Hecht, documents showing what ZHP did, prior to making the change, to assess the changes that were made?
A. Which change are you talking about now?
Q. Sorry, good question. Let's start with the TEA with quenching.
Did you ask to see any documents that describe the steps that ZHP took to assess that process, prior to making the changes?
A. I'm sorry, but I really don't understand what you're talking about, okay?
Q. I'm asking -- let me --
MR. BERNARDO: Let's pull, let's pull up one of the documents here. Let's pull up what I'll mark as --
MR. SLATER: Rich, are you talking about an assessment --

Page 108

MR. BERNARDO: I'm going --
MR. SLATER: -- in general, or are you talking about an assessment of the specific parts of the reactions that Dr. Hecht has been focusing on?
MR. BERNARDO: There's no question on the table to ask that about.
MR. SLATER: Well, we're not trying to trick anyone we said. Right?
MR. BERNARDO: Adam, there's no question on the table for which you can object.
Are you going to pull up --
MR. SCHOCH: Okay.
Q. Okay. I'm pulling up and going to mark -- this was already marked, right? This was Exhibit 5, right? This was the amendment to the Drug Master File.
I forget whether you've said you have seen this before or not. Would you refresh my recollection, Dr. Hecht?
A. Maybe.
Q. Maybe you've seen it. Okay. This is a document that was submitted to FDA. Correct?
A. Yes.
Q. Okay. And there are multiple sections analyzing if you --

Page 109

MR. BERNARDO: Again, have we figured out if the doctor can have a look at this document on his own. This makes this sort of clunky.
Q. Dr. Hecht, are you able to pull up documents, has that been sorted through?
A. I haven't tried, I mean.
Q. Well, let's just take a look at the changes. And the first change we discuss is on page 3 to 4, page 2 of document. Right?
A. Yeah.
Q. And we looked at this before. And we looked at -- if you look at Table 4 -- I'm sorry, Table 1 on page 4 of 8, right, it gives you data that the company compiled. And they used that data to determine that the process leads to equivalent yields and impurity levels.
Do you see that?
A. Yes.
Q. And this is under --
MR. BERNARDO: If you scroll back, Josh.
Q. A section called "Justification and Risk Assessment." Correct?
A. Yes.
Q. And is it fair to say that this document demonstrates the steps that the company took to

Page 110

determine whether this was an appropriate or not-appropriate change?
A. Yes.
Q. Okay. So they did take steps, that's really all I want to establish, to evaluate the change. Correct?
A. Yes.
Q. Okay. And if you look -- there's another assessment on page 4. Okay? And it says, "After reaction" -- I'm sorry. "No adverse change in qualitative and quantitative impurity profile." Correct?
A. Yes.
Q. Okay. So they -- the point I'm trying to make sure we agree on is that ZHP didn't simply make changes to the process; but they evaluated the changes they were making, to see if they were appropriate changes to make.
Do you agree with that point?
A. No.
Q. You don't think they took any steps whatsoever to evaluate the changes that they were making?
A. They didn't take the right steps.
Q. Okay. Now I think I understand --

Page 111

A. I can take all kinds of different steps to evaluate a process that are meaningless. They didn't take the critical steps.
Q. Okay. So it's your testimony that the steps that ZHP took in the risk assessment they did were meaningless?
A. No. They're meaningless with respect to the formation of nitrosamines in their product.
Q. Okay. So --
A. That's the risk assessment that they should have taken.
Q. Got it.
A. One of them. Which they did not take.
Q. Okay. So that's the risk assessment, in your opinion, that particular one: To evaluate DMF, and whether or not it degrades or how it gets used. Correct?
A. They should have looked for nitrosamines in their product.
Q. Okay. But again, to clarify --
A. They're using sodium nitrite. That is the step that they should have taken.
Q. Okay.
A. They were oblivious.
Q. Okay. Dr. Hecht, whether it's your

Page 112

opinion that they were oblivious or not as to one aspect, you will agree, based upon what we're looking at, we could look at more if you'd like, that they did take steps to evaluate the risks of the changes?
MR. SLATER: One second before you answer, Doctor, I just want to object.
Because you characterized the statement as "oblivious" as an opinion. I believe it's a stipulated fact, per the stipulation entered into this litigation, so I think that that question is inappropriate.
MR. BERNARDO: Okay. We'll have to look at the stipulation again. But that's -- despite that, I think it's an appropriate question.
Q. And if you would answer it, Dr. Hecht?
A. Okay. So what's the question again?
MR. BERNARDO: Can you read the question back, Ellen?
(The testimony is read back.)
A. No. No, that's not -- it's taken out of context. That's not my opinion. It's not my opinion that they were meaningless. What I said was they were meaningless with respect to the formation of nitrosamines in their product.
Q. Understood.

Page 113

A. They were not necessarily meaningless, with respect to other aspects of risk.
Q. Correct. So they -- again, I understand what you're saying: That there's one, in your view, important piece that they did not look at. But you're not -- it is -- would you agree that they did take steps to evaluate the risks of their changes, prior to making those changes, and submitted those evaluations to FDA through the document that we're looking at?
MR. SLATER: Objection to the form of the question.
You can answer.
A. Yes. I don't know about risk. But yeah, they submitted the changes to the FDA; they have to do that.
Q. But they submitted more than just changes, Dr. Hecht. That's what I want to see if you agree or disagree on. They submitted more than -- they didn't just say, "I'm changing this to this." They said, "I'm changing this to this, and these are the steps we took to determine that those changes are appropriate."
Do you agree with that general characterization?

Page 114

A. Yes.
MR. SLATER: Objection.
You can answer.
You know, Dr. Hecht, most people aren't quicker than me. You're pretty quick on the draw there.
Q. I want to take a look at -- let's mark --
MR. BERNARDO: Actually, why don't we -- I think we've been going about an hour. Why don't we take a break before I turn to a new topic here, and cut it in the middle.
THE VIDEOGRAPHER: All right. Going off the record. The time is 10:34 a.m., Central Time. This is the end of Media Unit 2.
(A brief recess takes place.)
THE VIDEOGRAPHER: We're back on the record. The time is 10:48 a.m. Central Time. This is the beginning of Media Unit 3.
BY MR. BERNARDO:
Q. Dr. Hecht, you would agree that pharmaceutical manufacturers would not be expected to test for every conceivable impurity. Is that a fair statement?
MR. SLATER: Objection.

Page 115

You can answer.
A. I don't know what you mean by "every conceivable impurity." I mean, sure, there are priorities.
Q. But roughly how many potential impurities could there be that could contaminate a product, in the world of impurities?
MR. SLATER: Objection. Are you asking in the world of every product that is manufactured around the world? Are you talking about with this --
MR. BERNARDO: I'm asking a general question.
MR. SLATER: All right.
So you --
MR. BERNARDO: Adam -- Adam, I think the objections are getting a little over the line. I'm trying to just not go back and forth. I think there's been a hearing with the judge on this, and I'm -- you know -- let's just --
MR. SLATER: I don't think --
MR. BERNARDO: If the doctor has -- if the doctor has a question about my question, or thinks it's not clear, he can ask me. If you have an objection to form, you can tell me you think the question is vague, and I can go on. But I don't

Page 116

think you can go and give the 12 versions of what you think my question could possibly mean. Let's move on.
MR. SLATER: Well, I didn't --
Q. Dr. Hecht, Dr. Hecht --
MR. SLATER: Hang on, hang on. Hang on, Mr. Bernardo. I'm trying to answer you. You're not going to -- I'd appreciate it. I'm not talking over you; please don't do that to me.
I didn't give the 12 versions of your question. I asked you to clarify an improperly asked, lack of foundation, ambiguous question. That's what I did. And I tried to help you to make it clear, because it's not a usable question. So don't mischaracterize what I did, please.
MR. BERNARDO: Adam, I would appreciate if you would be governed by what you need to do to represent your client --
MR. SLATER: I am doing that.
MR. BERNARDO: -- instead of -- let me finish now. Instead of helping me. Okay? I think --
MR. SLATER: Do me a favor. Let's neither of us will lecture each other. I'll make my objections; you don't like what I'm doing, you

Page 117

always -- you have many -- you can do what you think you need.
MR. BERNARDO: And that's what I just did. I'm telling you: I feel like you're getting, if not over the line, close to the line. I don't feel as if we need to get the Court on the phone. I'm simply, as a courtesy, telling you what my opinion is, as to the extent to which you're invading this deposition. So let's move on.
BY MR. BERNARDO:
Q. Dr. Hecht, do you agree that -- first of all, what I was asking when we got interrupted here, was: If you consider the world of impurities that could affect a potential pharmaceutical, a single pharmaceutical, we're talking about there could be, you know, hundreds, if not thousands, of potential impurities that could affect something or contaminate something. Is that -- is that a fair statement?
MR. SLATER: Objection.
You can answer.
A. I don't know about the number that you gave. Of course, there can be on different impurities.
Q. Okay. And --
A. But I don't know about -- I wouldn't say

Page 118

hundreds or thousands. That's -- I don't -- well, I don't -- I don't think that's a good way to put it.
Q. Okay. Would you agree that there should be a reasonable chance that an impurity can form, before the pharmaceutical manufacturer, in your opinion, would be expected to test for the impurity?
MR. SLATER: Objection.
You can answer.
A. Not in this case. You'll never get me to agree to that.
They're dumping in nitrate at pH[redacted]. They have to test for nitrosamines, absolutely.
Q. In your opinion, because there was a reasonable chance it could form; or just, period?
A. No, a reasonable chance that they could form. Absolutely.
Q. Okay. So you would agree that, I think, that there would have -- you think there was a reasonable chance that nitrosamines could have formed. I understand that testimony, right?
A. Yes.
Q. Okay. But that then would suggest you agree with me: That in order to test for something, there ought to be a reasonable chance that it could form. Is that fair?

Page 119

MR. SLATER: Objection.
You can answer.
A. I don't know about "anything." Okay? I don't know why you're extending this to, you know, to all things. I mean -- that's, to me is like -- well, I don't know. I mean, I'm just saying that in this particular case, where they're adding sodium nitrite at pH[redacted], they should have tested for nitrosamines.
Q. I want to give you a hypothetical, so I want you to assume that -- and I know this is different than your opinion, Dr. Hecht, but I want to assume for my question that ZHP had no knowledge that nitrosamines could form. Okay?
Are you with me on the assumption?
A. Yeah.
Q. Okay. Under those circumstances, you would not expect them to test for it. Is that fair?
MR. SLATER: Objection.
You can answer.
A. Yeah, I guess. You know, if there was no reason to think that nitrosamines would form, then, you know, there would be -- probably would be no reason to test for them. I mean, you can't test for every contaminant that could possibly be in a

Page 120

drug, because, you know, there are just too many.
So, you know, they do -- you do have to be a little focused, and that's where awareness and knowledge come in. That's where awareness of risk, knowledge of possible risks, enter into the picture. And, you know, that differentiates a responsible, knowledgeable chemist from one that is unaware.
Q. Thank you, Dr. Hecht.
MR. BERNARDO: I want to put up as exhibit, I'm sorry, Adam -- I don't know why I called you Adam? Josh, what number are we up to? Yeah, Adam is right, it's hard, it's difficult; there are big numbers here. I want to mark as Exhibit 9 an August 30, 2018, statement from the FDA.
(Exhibit Hecht-9, FDA Statement entitled, "FDA Statement on FDA's ongoing investigation into valsartan impurities and recalls and an update on FDA's current findings" dated August 30, 2018, No Bates, Six Pages, was received and marked for identification.)
Q. Okay. So Dr. Hecht, as you see, this is an FDA statement, and the title is: "FDA statement on FDA's ongoing investigation into valsartan impurities and recalls and update on FDA's current findings."

Page 121

And it says, "For immediate release," from -- I'm sorry, on August 30, 2018, from Scott Gottlieb. Do you see that?
A. Yes.
Q. Have you seen this document before?
A. It does not look familiar. I don't know if I've seen it.
Q. Okay. And are you aware that Dr. Gottlieb, at the time, was the FDA Commissioner?
A. Yes.
Q. Okay. And if you -- and this is a document, and if you want, you can scroll through it or have us scroll for you, but I really want to focus on a statement that's made at page 4 of the document?
A. Okay.
Q. And this is a document, you would agree, that was issued, or a statement issued by FDA, by way of follow-up to the discovery of nitrosamines in 2018 in valsartan. Right?
A. So it would appear.
Q. Okay.
MR. BERNARDO: Are we on page 4? There we go.
Q. I want you to read the sentence, and like --

Page 122

MR. BERNARDO: Yeah, exactly. If you un-highlight it, it's easy for him, Josh.
Q. My colleague highlighted the beginning, "Because."
A. Yeah.
Q. I'm sorry, would you read it into the record?
A. Yeah. "It was not anticipated."
Q. Sorry. Would you read the whole sentence into the record, and then I'll ask you a question about it?
A. Okay.
"Because it was not anticipated that NDMA would occur at these levels in the manufacturing of the valsartan API, manufacturers would not have been testing for it."
Q. Okay. So in this document, the FDA Commissioner is explicitly stating that it was not anticipated that NDMA would occur at these levels in the manufacturing of valsartan. Correct?
A. That's what he's saying.
Q. And because of that, the Commissioner of the FDA was saying, and for that reason, drug manufacturers would not have been testifying -- would not have been testing for it.

Page 123

Is that what he's saying?
MR. SLATER: Objection.
You can answer.
A. That's what the sentence appears to say.
Q. Okay. Do you disagree with the FDA Commissioner's statement here?
A. Absolutely disagree.
Q. Okay.
A. A hundred percent.
Q. Okay. So you think the FDA was wrong when it said this to the public?
A. Yes, it should have been testing for it.
Q. Okay. So let's take a look at another statement.
MR. BERNARDO: And this is marked as Exhibit 10.
(Exhibit Hecht-10, FDA Statement entitled, "FDA Statement on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency's steps to address the root causes of the safety issues," dated January 25, 2019, No Bates, Five Pages, was received and marked for identification.)
MR. SCHOCH: Uh-hum.
MR. BERNARDO: Oh, sorry, the

Page 124

January 25, 2019.
Q. And this is a statement, it looks like it's issued several months later from FDA, January 25, 2019, also from Scott Gottlieb, M.D., the Commissioner. Do you see that?
A. Yep.
Q. And it's another statement FDA issued as they were continuing to investigate the nitrosamine formation in valsartan. Is that correct?
A. Yes.
Q. Again, if you need to look at it, you'll let me know, but let's just jump ahead to page 3, and I'll show you the section about which I want to ask you a question.
So where my colleague highlighted, and he'll take that off so you can better read it --
MR. BERNARDO: Thank you.
Q. Can you just read that sentence?
A. Yeah.
"Tests are selected based on assessments of what impurities may develop as a result of the manufacturing process. In other words, it generally needs to be recognized that there's a risk of an impurity occurring as a result of a manufacturing process to know the impurity should be tested for."

Page 125

Yes, right.
Q. And I think you would agree with that, based upon what you said. Correct?
A. Yeah, right. They should have tested for it.
Q. Okay. Is it your expectation that pharmaceutical companies generally test for NDMA or NDEA or other nitrosamines?
A. Not generally, no. I don't think they do.
Q. Okay. To your knowledge, prior to 2018, did pharmaceutical companies regularly test for NDMA or NDEA or other nitrosamines?
MR. SLATER: Objection.
You can answer.
A. I do not know.
Q. I'm sorry, I didn't hear your answer?
A. I don't know.
Q. Would that be relevant to your opinion, with respect to how widely-known, and how any chemist in a manufacturing process would be expected to know, if other manufacturers didn't test for NDMA or NDEA in pharmaceuticals?
MR. SLATER: Objection.
You can answer.

Page 126

A. My opinion is based on knowledge of the literature, and on decades of research on nitrosamines that has established them as some of the most potent carcinogens that are present in various situations that humans are exposed to. So my opinion is well formed on that, with respect to nitrosamines.

So if I were the FDA Commissioner, and I saw this process, I would tell the company that they had to test for nitrosamines.

Q. Okay.

A. Specifically for nitrosamines.

Whether nitrosamines should be tested in all drug substances, it's probably not necessary; because the manufacturing process, in probably the vast majority of cases, would not involve the use of sodium nitrite in the presence of secondary amines at pH[redacted]

(Court Reporter Clarification.)

MR. SLATER: He said -- I'll tell you. He said, "the presence of secondary amines at pH[redacted]"

A. Very few pharmaceutical companies would venture to use that kind of chemistry, okay? Because the people in pharmaceutical companies, they're not idiots, they're aware of the literature. Okay? There's hundreds of published papers on the

Page 127

carcinogenicity of nitrosamines. There's multiple reviews. There's conferences that have taken place for years, okay? So this is -- this is not something that's -- this is something that's widely known, let's put that way.

And organic chemists and pharmaceutical agents -- pharmaceutical companies should be aware of it. They are aware of it. All right? Because I mean, the FDA has had committees on nitrosamines. FDA started their meetings on nitrosamines in the 1970s. Okay? So this is not a niche issue; this is a well-known issue. But ZHP was not thinking or -- whatever. I don't know.

Q. There are many different kinds of nitrosamines in chemistry, fair to say?

A. Yes.

Q. So for example, there are tobacco-specific nitrosamines; that's one kind. Correct?

A. Yes.

Q. There are nitrosamines that could be formed during the -- the curing or grilling of meats and other foods, and nitrosamines that go in foods. They're all different, and have a different mechanism for formation. Is that fair?

Page 128

A. Sure.

Q. Okay. And I just want to establish: What you're talking about was, generally with respect to the development of nitrosamines; not specifically the development of nitrosamines in pharmaceuticals. Fair, in terms of the wide knowledge?

A. Yes, generally. But pharmaceuticals is one aspect of it, okay? And people -- investigators, chemists from drug companies, pharmaceutical companies, attended the meetings that discussed nitrosamine formation. Okay? They attend the American Chemical Society meeting, where nitrosamine formation, nitrosamine formation, nitrosamine carcinogenicity, nitrosamine chemistry is discussed. So they are aware.

Q. Are you aware, have there been any of these types of conferences that you're aware of that discussed the development of NDMA or NDEA, under the conditions that were present in the processes we've discussed today?

A. Starting in 1970, sure.

Q. So you're saying that the formation of NDMA, for example, in a process like the zinc chloride process, has been the subject of a conference since the 1970s?

Page 129

MR. SLATER: Objection.

Q. I want to understand what you are saying has been in a conference?

A. Not specifically --

MR. SLATER: One second, Doctor --

(Simultaneous speaking.)

A. No, not specifically for this process, okay? I'm saying the general mechanism of formation, okay? So that is the beauty of chemistry, okay? You have certain reactions that will take place under certain conditions, and it doesn't matter whether that's in a food product or a pharmaceutical product, or in the environment. Okay? We can predict that that reaction will take place.

And the formation of dimethylnitrosamine from dimethylamine has been known for decades.

Q. Okay. I want to go back to your report for a moment, and we're going to put on the screen, page 20. And I want to have you take a look; it's about five, six lines from the bottom.

"In their analyses of the product, they would not have identified NDMA in the chromatograms unless they were specifically looking for it, because the peaks would be too small."

Do you see that?

Page 130

A. Yep.
Q. Okay. And I understand you follow-up by saying that that's not a legitimate scientific excuse. I want to ask you a question.
Hypothetically, if ZHP was not expected -- sorry. If nitrosamine formation would not be expected, you'd -- you agree, there's no reason they should have detected it in their products with the testing that was done. Correct?
MR. SLATER: Objection.
(Simultaneous speaking.)
MR. SLATER: That doesn't make sense.
A. They wouldn't have seen it. Not in routine testing.
Q. Okay. And now you say ZHP should have been testing its API for both NDMA and NDEA. Is that correct?
A. Yes.
Q. Is it your opinion that ZHP should have been testing for all nitrosamines, or just those two?
A. Well, those would be -- those would be the main two. But I mean, again, they're adding nitrite at pH [redacted] this is like perfect conditions for nitrosamine formation. You can read it in the literature. It's been known since the 1950s, all

Page 131

right?
So, you know, if there were other secondary or even tertiary amines present in their reaction mixtures for whatever reasons, then other nitrosamines possibly could have formed.
Q. Now fair to say, Doctor, you've never worked at a pharmaceutical company. Correct?
A. Yes.
Q. That's correct, you haven't worked at one. Right?
A. Correct.
Q. Thank you. And you've never done any kind of systemic evaluation of the kind of testing or testing program that a pharmaceutical company does. Correct?
A. That's correct.
Q. Okay. So fair to say, you're not an expert in testing pharmaceuticals for impurities?
MR. SLATER: Objection.
A. Well, I know how to do it. All right? I just haven't worked in that area. But I certainly know how to do it.
Q. Right. But you're not an expert in terms of what is done or what should be done, or the types of equipment that are typically used or not

Page 132

used. Is that fair?
MR. SLATER: Objection.
(Simultaneous speaking.)
A. Well, I know what should have been done in this case. Absolutely, I'm an expert.
Q. But I'm talking about in the category of testing pharmaceuticals generally, Dr. Hecht?
MR. SLATER: Objection --
A. I don't know what you mean. I mean, if I saw this process, I don't care whether I'm in the pharmaceutical industry or wherever I am; I would take this material into the lab and test it for nitrosamines.
Q. Okay. So gas chromatography, GC, is a type of chromatography that's used in analytical chemistry for separating and analyzing organic compounds that can be vaporized without decomposition. Is that fair?
A. Yes.
Q. Okay. And would you agree that -- can I just call it "GC"?
A. Yes.
Q. Thank you. You would agree that GC is routinely used by chemists to test the purity of a substance?

Page 133

A. Yes.
Q. Okay. And GC can be followed by a couple detectors, such as a flame ionization detector?
A. Correct.
Q. Okay. Which I'm going to refer to as FID, if that's okay?
A. Right.
Q. And the FID is an analytic instrument that measures analytes in a gas stream?
A. Yes.
Q. And FID functions by detecting ions that are formed during combustion of organic compounds in a hydrogen flame?
A. Yes.
Q. And you agree that the combination, which I'll refer to as GC-FID, is commonly used by chemists in separating and analyzing organic compounds that can be vaporized without decomposition?
A. Yes.
Q. And you agree that GC-FID can detect almost all carbon-containing organic molecules?
A. I wouldn't go that far.
Q. Where do we depart?

Page 134

A. They have to be volatile.
Q. Okay. That would be your qualifier?
A. Well, the detection method is pretty general, but it wouldn't work unless you -- you have to convert the analyte into the gas stream of the -- of the GC. If it's not volatile, it wouldn't go through the GC.
Q. Thank you. And you would agree that there are articles that have been published in the peer-reviewed scientific literature about GC-FID as an analytic tool. Correct?
A. Yes.
Q. Okay. Would you agree that it's become the most widely-used tool for volatile organic compound detection?
A. It's one of the most volatile -- volatile? It's one of the most widely used.
Q. Okay. But if there's an article -- again, I'm trying to just be efficient and not have to go through it -- that stated that it's become the most widely-used tool for VOC detection, you wouldn't have a reason to dispute that. Correct?
A. Yes.
MR. SLATER: Objection.
Q. You -- I think you agreed with me,

Page 135

Dr. Hecht, but I just want to make sure?
A. It's one of the most widely used. I don't know if it's the most widely used anymore. But it's definitely one of the most widely used. But you know, GC mass spec has taken over.
Q. And --
A. You know, there's always evolution of analytical methods. And, you know, the older ones fall by the wayside, new ones come along. And the new ones are usually pretty expensive at first, but, you know, as further advances are made, they also become cheaper and they take over. It's just like any product.
Q. Sure. As science evolves, so too does technology. Right?
A. Yep.
Q. And again, I'm just trying to be efficient, because if you do disagree, we can pull it up and take a look at it. But if there were an article that were published that -- in 2016. And by the way, let me take a step --
MR. SLATER: I'm sorry, can you show him the article? I don't really understand what you're doing here.
MR. BERNARDO: I'm just asking a

Page 136

question. Okay?
MR. SLATER: I get it, but I'm asking you to show him the article, rather than asking him to assume that articles say things.
MR. BERNARDO: Okay.
Q. Dr. Hecht, first of all, you agree what we're looking at really should be -- what we're evaluating should be what was in use in 2000 -- before 2018. Correct? Because that's the period of time that we're talking about. Is that fair?
A. Right.
Q. Okay.
MR. BERNARDO: So why don't we pull it. I was trying to be efficient. Why don't we just mark this.
(Exhibit Hecht-11, Article entitled "High performance mini-gas chromatography-flame ionization detector system based on micro gas chromatography column," from Review of Scientific Instruments, published April 21, 2016, was received and marked for identification.)
Q. And this is a 2016 article entitled, "High-performance mini-gas chromatography-flame ionization detector system based on micro gas chromatography column."

Page 137

I'll ask the question, but I can't imagine you'll remember.
Do you know if you've had occasion to review this article before?
A. Have I what?
Q. Had occasion to review this article before, if you know?
A. No, I haven't seen this one.
Q. Okay. Why don't we just take a look at the second page, the bottom left. Okay. I simply -- and again, you're welcome to look at as much or as little of this off the record as you'd like. But I just want to see if you have any reason to dispute -- you see this --
MR. BERNARDO: You want to get the bottom left since the N --
Q. If you look at that last paragraph -- whoops, there we go, the last paragraph on the left-hand column that begins "Since the advent"?
A. Yup.
Q. Okay. Can you just read that?
A. "Since the advent of the flame ionization detector, it has become the most widely-used tool for VOC detection."
Q. As you sit here today, Dr. Hecht, I just

Page 138

want to understand: Do you have any reason to dispute that conclusion?
MR. SLATER: Objection.
Q. This is a 2016 article?
MR. SLATER: Objection.
You can answer.
Asked and answered.
You can answer again.
A. Yeah, I have reason to dispute it, because I think GC mass spec might be just as widely used. I don't know, I don't have the figures before me. But, you know, GC mass spec is certainly widely used. I think all universities have it, and I'm sure all pharmaceutical companies have it. And all industry has it.
I mean, you know, it's hard to imagine doing analytical chemistry these days without a GC mass spec or LC mass spec.
Q. And --
A. So yeah, whether GC-FID is more widely used than GC mass spec, I'm really not sure.
Q. Thank you, that's all I'm asking. And this -- I just want to make sure we're on the same page, literally. That we're in -- this is an article in 2016, I'm not asking you about today, I'm asking

Page 139

you about 2016.
Is your answer the same for 2016 as you just gave me. Correct?
A. Yes.
Q. Okay. Thank you. Would you agree that there are actually times when --
MR. BERNARDO: You could take that down.
Q. When GC-FID is, in fact, the best method for testing?
MR. SLATER: Objection.
You can answer.
A. That's a really hard question to answer. I mean, I don't know what you're driving at. The best method? I mean, the best method for what?
Q. Fair enough. I'm simply asking whether you would acknowledge that there are circumstances in which this could be the best method to use. I'm not asking you to delineate them.
And if you don't know, you don't know?
MR. SLATER: Objection.
You can answer.
A. Yes, I suppose there are circumstances where GC-FID could be a better method than GC mass spec.
Q. Have you, Dr. Hecht, ever tested for

Page 140

impurities using GC-FID?
A. Yes.
Q. Have you ever tested for impurities using GS [sic] mass spectrometry?
A. Yes.
Q. I want to go back to Dr. Xue's report, which we'll put on the screen?
MR. BERNARDO: And if Josh, you could turn to page 53.
Q. And I'll just tell you in advance: The purpose of this question, Dr. Hecht, is just to get an understanding. I think there's certain things that you and Dr. Xue agree with, and I know there's certain things you disagree with, and I just -- I'm trying to distinguish or understand the difference.
So page 53, the last line, it says, "The five methods" -- I'm sorry.
"Plaintiff's experts also state that five testing methods for nitrosamines were available, and any reasonable organic chemist would have used one of them to test valsartan API for nitrosamines."
That's a fair characterization. Correct?
MR. SLATER: I'm sorry. One second, Doctor.

Page 141

Are you saying, did you read the statement correctly?
MR. BERNARDO: I'm asking if it's a fair characterization.
Q. Do you agree with that characterization of the plaintiff's experts, in what they say?
MR. BERNARDO: So, no, Adam, I'm not asking if I read it correctly.
A. Five methods.
Q. No, I'm just on the first -- oh, yeah.
MR. SLATER: Are you including the footnote to that sentence?
MR. BERNARDO: Yes.
A. Okay. Five methods, I can't read the footnote, but I don't know --
MR. BERNARDO: Can you blow that up, Josh. Blow it up a little more. Thanks.
A. Yeah, I guess these are -- these are the five methods they -- that he's mentioning.
Q. Right. Okay. Just going on the carryover sentence, Dr. Xue says, "The five methods identified by plaintiff's experts include the combined head space method" -- and I'm going to skip over the abbreviations -- "combined direct injection method, direct injection, head space, and LC-HRMS

method."
Did I read that correctly?
A. Yeah, that sounds right.
Q. And those are the five methods that plaintiff's experts have pointed to. Is that fair?
A. Yep.
Q. Okay.
MR. BERNARDO: And can you move it up a little bit, Josh -- sorry. Sorry, I want to continue reading, thank you.
Q. And he also says, "All of these methods use MS," or mass spectrometry, "as a detector."
Do you agree with that?
A. Yes, that's right.
Q. Okay. Here's the part I want to see if you agree with.
"Although these methods" -- sorry.
"Although these MS-based methods are sensitive toward the nitrosamines NDMA and NDEA, I" -- and he's saying Dr. Xue -- "have not seen any evidence that they were the standard in the industry at the time when the zinc chloride process and the TEA process with quenching were being utilized for the production of valsartan API. And as I've explained above, ZHP did not have a scientific reason

to be looking for NDMA or NDEA in valsartan API at that time."
Did I read that correctly? That's all I'm --
A. Yes, you did.
Q. Okay. I want to eliminate the last part, because I know your position on there. I want to ask, Dr. Hecht, if you have identified evidence, and if so, what it is, that these methods that were described above were standard in the industry at the time when the zinc chloride process and the TEA process with quenching were being utilized for the production of valsartan API?
MR. SLATER: Objection.
A. Absolutely. GC-MS and LC-MS are standard in the industry. Absolutely, a hundred percent.
Q. And what is -- can you point me to something that would help us understand where you get to that conclusion?
A. I know from -- from my students or post docs that have gone into industry, they come back and tell me how well-equipped these pharmaceutical industries, pharmaceutical companies are. Okay? I mean, a mass spectrometer is a significant

investment, and it's not always easy for academic institutions to acquire them, because they can be quite expensive. But industry certainly, the pharmaceutical industry, absolutely, a hundred percent, has these instruments available.
I don't know where this guy gets his information from. It's absolutely wrong. Okay?
Q. And to be clear, Dr. Xue is saying he's not seeing evidence. And what you're pointing me to, if I understand, is commentary from your students. So this commentary from your students is from 2013 or prior?
A. I can't tell you exactly when it's from.
Q. I'm just trying --
A. Look, I know the pharmaceutical industry definitely is well-equipped for mass spectrometry. There's no doubt.
Q. In 2013?
A. Yes, in 2013. No doubt.
Q. Okay. And I understand you have no doubt. I'm trying to understand the reason you have no doubt, and you've told me because students you've had have come back and told you. Is there any --
A. That's not a good example, okay?
Q. Okay.

A. A better example is from, you know, I attend conferences every year of the American Chemical Society. I see the hundreds of papers that are presented, many of them from the industry, okay? I attend the conference, the American Society for Mass Spectrometry, ASMS, that happens every year, okay? They have hundreds of presentations, many of which are from industry, and all use these methods.
So I mean, I don't know where this guy gets his information from. It's wrong. It's absolutely wrong.
Q. Okay. I'm not asking whether or not they were used. I'm asking whether or not they were the standard in the industry, and I'm trying to understand --
A. Yes, they are the standard.
Q. Let me just finish. I understand that's your opinion, Dr. Hecht.
A. It's more than an opinion; it's a fact.
Q. Okay. I'm trying --
A. To be clear, okay? This is a fact.
Q. Okay. Is it a fact because you say it's a fact, or is it a fact because you can point me to a process to be determined --
(Simultaneous speaking.)

Page 146

(Court Stenographer clarification.)
Q. Wait. Wait, Dr. Hecht --
A. Go to the abstracts of the American Society For Mass Spectrometry, ASMS, which are published every year. Look at the hundreds of abstracts and where they come from.
Q. Okay.
A. And you'll find your answer.
Q. Okay. I don't want to -- I don't intend personally to research this. I'm simply trying to ask if you've done: -- have you done anything to research this, or are you saying it based upon your observations?
A. It's based on my observations. I've attended the ASMS meetings.
You know, I was editor-in-chief of Chemical Research and Toxicology for five years, so I see all the papers that are submitted, many of which come from industry, and they use this technology.
Q. Dr. Hecht, what did you do to prepare for your deposition today?
A. I studied the binders.
Q. And the binders are the ones that you referred me to that include approximately four binders of ZHP documents, and some other materials?

Page 147

A. Yes.
Q. Okay. Generally, in respect to forming your opinions in this case, did you read deposition testimony?
A. Yes, I did read a couple.
Q. And did you read the depositions in their entirety, or did you read -- read portions of them?
A. I don't really know.
Q. Okay. Well, you cite to some of them, so I'm trying to understand a little bit better.
A. Yes, so I mean, I have the deposition of -- I don't know. The guy...
MR. SLATER: Take your time, there's no rush.
Q. Let's do it this way, Dr. Hecht. You've cited to certain ones, and we don't need to get into the specifics. I'm really just trying to get a general sense.
A. Yeah, well, I'm looking for the deposition of -- I don't know; I can't find it right now.
Q. Okay.
A. Anyhow, there's a guy from industry that talked about the various analytical methods that were

Page 148

used, and then, you know, he showed the various different peaks that you could get from GC-FID, and, you know, the peaks were very small for NDMA, and blah-blah-blah, and -- whatever. It's irrelevant, I mean -- well, it's not irrelevant. It's relevant.
But the point is that, in order to get a firm handle on the quantitation of NDMA or NDEA at these levels, you're talking about like an average of 65 parts per million or whatever, you're going to have to use a mass spec detector, a GC-MS.
Q. Yeah, I'm on a different topic, Dr. Hecht, just let me help here. So I moved past the testing methodology, and I really want to just understand what you, Dr. Hecht, did to form your opinions in this case.
And remember, I'm talking about your opinions in your December 2022 or your October '22 report and just a portion of your 2021 report that we talked about earlier. Are you with me?
A. Yep.
Q. Okay. Before you formed your opinions as to what ZHP did or didn't do, or knew or should know, those opinions, did you review testimony of ZHP employees?
MR. SLATER: Objection.

Page 149

You can answer.
A. Could you rephrase that? I mean, that's --
Q. I'm simply asking --
A. I don't really know -- try to rephrase it, okay?
Q. Of course. In connection with the portion of your report we've talked about, okay? I just want to make this a simpler question.
So you do remember our discussion at the beginning of this deposition, that I'm only asking you questions about your ZHP-specific opinions, the ones that are in your 2022 report, and in a portion of your 2021 report. Are you with me on that?
A. Yeah.
Q. Okay. So those opinions, in connection with forming those opinions, did you review testimony, deposition testimony, of ZHP company employees?
MR. SLATER: Objection.
You can answer.
A. Yes.
Q. Okay. Approximately how many employees' depositions did you read?
A. I don't know.

Page 150

Q. Okay. Do you know if you read the entire testimony of the employee, a portion of the testimony of the employee? Like, did you sit down and say, "Here, I'm going to read this particular person from cover to cover"; or did you just look at portions of it?
A. Portions.
Q. Okay. How did you identify which portion to take a look at?
A. You know, I have binders that have portions of testimony in them.
Q. Okay. And who selected --
A. That were sent to me.
Q. So you didn't select the portions of the testimony that you were going to review; somebody else selected them for you. Is that fair?
A. Yes.
Q. Okay. About how much time would you say you spent, just looking at deposition testimony?
A. Oh, I don't know. Several hours.
Q. Okay.
A. I don't know.
Q. Did you -- it's fair to say -- I'm sorry?
A. Yeah, go ahead.

Page 151

Q. Fair to say, you didn't interview any company employees yourself. Correct?
A. Correct, yes.
Q. Did you ask Mr. Slater if you could?
A. No.
Q. And did you write your report yourself, or did somebody else write it for you? What would -- help me understand the process?
A. I wrote the draft.
MR. SLATER: Wait, wait, time out. Time out. Stop for a second.
I got distracted for a second. Objection. You're not going to ask these questions. It's off limits, it's the work product. You're not asking about the writing of the report. You're not asking who wrote, who did what. That's it. Move on to the next subject.
MR. BERNARDO: I'm not asking anything about lawyers, I'm simply asking if Dr. Hecht wrote it or if he had somebody else write it. I think --
MR. SLATER: Objection. You can go to the Court. It's work product. How the report is written is work product; you know better. Come on.
MR. BERNARDO: Okay. I disagree with your characterization.

Page 152

MR. SLATER: Really? Do you want us to ask your experts --
MR. BERNARDO: Adam --
MR. SLATER -- who wrote their reports?
MR. BERNARDO: Adam, let's just have some ground rules. You don't -- I don't interrupt you when you're talking, let me finish my response, and then you can respond to that. It will make this much easier.
We will move on. I disagree with you. Let's move on.
MR. SLATER: Okay. And what I was saying, before you interrupted my interruption of your interruption of my interruption of you, was that's -- we're not going to be asking your experts that either, because it's clearly off-limits under the federal rules of civil procedure and the case law. Come on.
MR. BERNARDO: I disagree with that, but I'm happy to move on.
MR. SLATER: Okay. Are you suggesting when we depose your experts, we can ask them who had input into the writing of their reports?
Q. Dr. Hecht --
MR. BERNARDO: Adam, you're eating into

Page 153

my time, let's move on.
BY MR. BERNARDO:
Q. Dr. Hecht, did you read Dr. Bain's expert report?
A. Spell it?
Q. B-A-I-N? I think it might be it's B-A-I-N-S, but --
A. I don't know. What was it about? I don't remember.
Q. Okay. You answered my question.
So you don't know if you reviewed Dr. Bain's report before your report was written. Correct?
MR. SLATER: He doesn't know if he even saw it.
A. I don't know. I may have. I mean, I don't know how to answer it, because you have to tell me what was his report about. I don't remember the name necessarily. Who is Dr. Bain? I mean...
Q. You've answered my question. Thank you.
MR. BERNARDO: So Adam, I'm about to turn to a section that's not going to get done in a few minutes. It's 12:35, we're a little shy of an hour, but I'm thinking maybe now is a good time to take a lunch break. But that depends. We're an hour

Page 154

behind for Dr. Hecht, so maybe --
MR. SLATER: So hang on, hang on. This is what I'd like to do. I want to leave it up to Dr. Hecht. We're not doing an eleven --
MR. BERNARDO: Yeah, of course.
MR. SLATER: Because what I'm not doing is an 11-and-a-half-hour deposition today, like happened last night. You were fortunate enough not to be on the deposition. It went 'til 8:30; it started at 9:00 in the morning here on the East Coast. It went on forever.
So I just -- whatever breaks we take, I don't want to take them just for the sake of taking them. So I would ask the doctor if he wants to take a break, when he wants to take it, how long he needs. Because I really don't want to have this deposition going to 8 o'clock tonight.
MR. BERNARDO: I don't expect it will be, unless you have many hours of questions. I'm simply acknowledging that at some point in time, even if the doctor doesn't, there are other lawyers, myself included, who would want to take a break for lunch.
MR. SLATER: Well, I think the other lawyers, frankly, between you and me, they can eat

Page 155

while they watch. So I'm not --
MR. BERNARDO: I can't, and I'm not --
MR. SLATER: Look, it's 11:30 where he is. If Dr. Hecht is okay to keep going, we'd like to keep going.
MR. BERNARDO: Okay. Let's take, then, a brief bio break, and then we'll go for another hour, and then we'll decide about lunch. How's that?
Q. Does that work for you, Dr. Hecht?
A. Yes.
Q. Okay, thank you.
THE VIDEOGRAPHER: Going off the record. The time is 11:36 a.m. Central Time. This is the end of Media Unit 3.
(A brief recess takes place.)
THE VIDEOGRAPHER: We're back on the record. The time is 11:46 a.m., Central Time. This is the beginning of Media Unit 4.
BY MR. BERNARDO:
Q. Dr. Hecht, I want to change topics here, and we want to put back a copy of your report, or if you could take a look at a look at your report at pages 6 to 7. I just want to refresh your recollection about the subject I'm going to be talking about. Okay?

Page 156

MR. SLATER: What report did you say, Rich, the 2022?
MR. BERNARDO: Yes.
MR. SLATER: Thank you.
MR. BERNARDO: And it's on the screen.
Q. I want to focus, Dr. Hecht, on what is on the screen, which is your report that says, "A series of customer complaints was received by ZHP with regard to the unknown peak or aberrant peaks on the chromatography. And this includes" -- and then you list six -- seven pieces there.
Do you see that where I am?
A. Yes.
Q. Okay. And I think you refer to these as "customer complaints." Correct?
A. Yes.
Q. And you cite to various documents and testimony. Do you see that?
A. Yes.
Q. And this is -- these are -- well, let me go back.
So the deposition testimony just has excerpts. So for example, the first one says, "Quiangming Li," and it gives the date of the depo, and it has page 130, line 7, through 170, line 11.

Page 157

Correct?
A. Yeah.
Q. And those are ones I think we talked about earlier, is that the same thing here: Those are ones that plaintiff's counsel selected for you to take a look at?
A. Yes.
MR. SLATER: Objection.
You can answer.
A. Yes.
Q. And did you ask to look at any other parts of the deposition of those witnesses you cite, for context or other information?
A. I'm not sure I understand your question.
Q. Sure. I'll rephrase it. When you looked at, for example, the first reference we have under Number 1, it has, it looks like, 40 pages, maybe, right --
A. Sure.
Q. -- of testimony? When you read that, did you ask, based upon your reading of that, to see other testimony that would be relevant to that particular topic, or did you limit your review to those pages?
MR. SLATER: Objection.

Page 158

You can answer.
A. No, I didn't ask for more.
Q. And you cite to -- again, I'm just going to do it by way of example. For the first one, you cite to a single document.
Is it fair to say that that's the only document from the company that you looked at with respect to that particular issue?
MR. SLATER: Objection.
You can answer.
Q. I'm sorry, I didn't hear your answer, Doctor?
A. Yes.
Q. So, as you were looking at these, you didn't look at other documents that might pertain to the same circumstance. Correct?
MR. SLATER: Objection.
You can answer.
A. As far as I recall.
Q. Okay. And did you do any -- did you take any other steps to investigate the circumstances regarding the seven, I'll call them, as you do, customer complaints that are listed in your report, than look at the deposition excerpt and the documents cited?

Page 159

A. Any other steps with respect to what?
Q. Did you take -- did you take any other steps to investigate what was done in connection, or said in connection, with those customer complaints?
A. Well, all the material that I reviewed was related to these complaints. So I mean, I don't really know what you're getting at.
Q. I'm really --
A. The whole thing I related. They're all, they're all related.
Q. Okay.
A. So yeah, I did take other steps. I read, you know, all the other reports.
Q. Right. Let me be more -- we'll get into one or two of these with specifics, and then we can pursue that.
We know that the seventh one was the identification of NDMA -- or NDEA. Correct? The Novartis, Number 7?
A. Yes.
Q. Did the other six pertain to customer complaints that were received with respect to nitrosamines?
A. I don't think they had identified the nitrosamines at that time. I'm not sure. I mean --

Page 160

Novartis was the one that identified it, as far as I know. So I'm not sure. I don't think the other ones -- I mean the other complaints, I think, had to do also with a lot of other peaks that were in the chromatograms.
Q. Explain to me, setting aside Number 7, how Numbers 1 through 6 play into your opinion or a factor or something you considered? Explain to me what the relevance of them is?
MR. SLATER: Objection.
You can answer.
A. Well, I think, you know, they indicated a general lack of care on the part of the manufacturer.
Q. Explain to me how they demonstrate a lack of care on the part of the manufacturer?
A. Well, I think they saw other peaks in the chromatograms. You know, I don't think -- I don't think the NDMA and NDEA had been identified at that time. But, you know, they saw -- they saw other peaks in the chromatograms, as far as I recall, that -- you know, that they didn't think they should be there. They indicate lack of purity.
Q. So the fact that there were other peaks indicates a lack of care of the company? I just want

Page 161

to make sure I'm not putting words in your mouth, and I want to understand what you just said?
A. No, a lack of -- lack of purity, I said. Not lack of care, lack of purity.
So, you know, they're getting the API from ZHP, they're going to check it and make sure it's pure. And that's not what they saw.
Q. So is it possible that there could be impurities that don't cause concern, and that, after investigation, are perfectly okay? Or is it your opinion that any impurity whatsoever demonstrates a lack of care?
A. No, there could be impurities that are, you know, not a -- not a matter for concern.
Q. And do you know whether any of these examples that you identified concluded that the peaks related to impurities that were of no concern? Do you -- do you understand my question?
A. I don't remember what all the peaks were, to tell you the truth. We'd have to go through them one by one. So, you know, some things would be concerning and others would not. But, you know, if I were one of these companies, I wouldn't want to see a lot of other peaks in stuff that's supposed to be pure.

Page 162

Because, you know, I'm going to incorporate this into my product; I'm going to check and make sure that it's pure.

Q. Would it change your opinion if the company addressed them and looked into them, and found that they were of no concern; or that the person who or customer who complained about them was satisfied? Would that -- would that change your opinion?

MR. SLATER: Objection.

You can answer.

A. Nothing is going to change my opinion about what happened in this main issue.

Q. I'm sorry.

A. Nothing will change my opinion about that. I can guarantee you that.

Q. You pointed out a problem with my question. Thank you, Dr. Hecht.

I meant would it change your opinion as to the relevance of -- to your opinions, of these particular customer complaints? In other words, if these customer complaints were investigated, and it was determined what these issues were, and it was resolved to the customers' satisfaction, would these complaints have any relevance, or factor into your

Page 163

opinion anymore? That's just what I'm trying to find out?

MR. SLATER: Objection.

You can answer.

A. Yeah, I mean, they saw some peaks. And, you know, if the peak turned out to be something that's, you know, of no concern, then, you know, there wouldn't be a problem.

Q. And you -- I think you said, you didn't do anything to investigate each of these six circumstances, other than to look at the excerpts and documents that you were provided. Is that fair?

A. Yes, that's correct.

Q. Okay. Why don't we just take one of them.

MR. BERNARDO: And let's pull up, what exhibit number are we at?

MR. SCHOCH: 12.

MR. BERNARDO: Okay, that works out. Let's take -- well, first of all, let's take the, I think it's called Vertex.

(Exhibit Hecht-12, Email Chain ending 2/28/2019 in Chinese Language, Bates ZHP02630924 through 2630925, was received and marked for identification.)

Page 164

Q. Do you know what Vertex is, Dr. Hecht?

A. They're a pharmaceutical company.

Q. Do you know where they fit, in terms of their relationship with ZHP? Are they a customer of ZHP?

A. I believe they are.

Q. Okay.

MR. BERNARDO: I'm sorry, Josh, I want to take a look at the document, Tab 22.

Q. And I want to show you the first document that you have cited in your report. It may be helpful, Dr. Hecht, if you have -- and I think you said you did have -- your report handy, just so you could just take a look at numbers, if you have your report handy and can be on the page we were just looking at. Which was --

MR. BERNARDO: Josh, what page?

MR. SCHOCH: Page 6.

Q. Which is page 6 of your 2022 report. Tell me when you're there.

A. Yeah.

Q. Okay. So we're going to pull up -- we have pulled up --

MR. BERNARDO: If you scroll down to show the Bates number, Josh.

Page 165

Q. The first one that you have cited there. Correct?

A. Yep.

Q. Okay. And you can scroll through, it's a two-page document. Presumably you reviewed this, since it's cited in your report. Is that fair?

MR. SLATER: I don't think Dr. Hecht is looking at the screen. I think he's looking for something.

A. Okay. Go ahead.

Q. Sure. This is the first document that you cite on Number 4, Vertex.

Do you agree with me? If you look at --

A. At Vertex, right.

Q. Okay. And I just want to understand what, if anything, in connection with this particular customer complaint you got from this particular document?

A. I don't remember. I'd have to look at it.

Q. We're looking at it now. It's --

A. Yeah, okay, I know, but you didn't show me anything so far.

Q. I guess that's my point. Is there anything substantively that you could derive from

Page 166

this document?
A. I don't remember. I have to look at it.
Q. I'm asking you to do that. Has your --
A. I'm looking at it, right. But it doesn't show anything. It's just like two pages.
Q. Okay.
MR. BERNARDO: Can you expand the size, Josh? Okay.
Q. My point -- and I think you're agreeing -- well, first of all, there are portions of this document that are in Chinese. That's fair, and we'll look at the translation?
A. Yeah.
Q. Okay. But I just want to confirm, you agree, and I think you just said that: This document doesn't tell you anything that would explain to you what happened with respect to this Vertex customer complaint. I think --
A. Not these -- not these two pages, no.
MR. SLATER: Objection.
Q. Thank you, okay.
MR. BERNARDO: Let's look at the translation of these two pages, Josh, which is 265A.
(Exhibit Hecht-13, English Translation of Hecht-12, previously marked ZHP-265A, was received

Page 167

and marked for identification.)
Q. Okay. This is the translation that has been used or provided.
MR. SLATER: It's cut off.
MR. BERNARDO: That's exactly how it was provided and used as a deposition exhibit. And this is the document, if you look the reference that's cited in his report. I didn't create this.
A. Well, there's nothing useful here.
Q. Okay. Let's take a look at the other exhibit, which is ending in Bates 926.
MR. BERNARDO: And we'll mark that as exhibit, whatever number we're up to.
(Exhibit Hecht-14, Document in Chinese Language previously marked ZHP-266, Bates ZHP02630926 through 2630927, was received and marked for identification.)
Q. And this document is also in Chinese, so I'll just tell you there's an English translation that was used, and that is part of this, so we'll just turn to that.
A. Yeah.
MR. SLATER: Objection.
A. I see it.
MR. BERNARDO: Do you want to pull up

Page 168

the English translation?
(Exhibit Hecht-15, English Translation of Hecht-14, Bates ZHP02630926 through 2630927, was received and marked for identification.)
Q. Okay. And this is the other document that you have cited. Correct?
A. Yes.
Q. Okay. What did you glean from this document that supports your opinion that these customer complaints showed a lack of care of ZHP? And we can scroll through; just tell us when to scroll down, Dr. Hecht, if you'd like?
A. Well, there's --
MR. SLATER: One second. One second. Doctor, one second.
Objection to the question. The foundation, the mischaracterization, and the method that you're proceeding through these documents, and the way you're asking the questions.
Now you can answer.
A. There are solvent residues -- in the, you know, in the API.
Q. And you agree, at least what I see, where you're looking at the top, am I correct, you're looking at the, "Samples provided found solvent

Page 169

residues not contained"?
A. What?
Q. Where did you conclude from this page that there were solvent residues?
A. Just go back to the previous page.
Q. This is page 1. There we go.
A. Okay. Go down --
MR. SLATER: Can you make it bigger, please?
MR. BERNARDO: Sure.
Am I understanding that Dr. Hecht's document share still doesn't work?
A. I can see it. I can see it fine. They said -- yeah. They found solvent residues.
Q. Okay.
A. "Not contained in the following Russian giant registration document." I'm not sure what that means.
Q. Okay. But based upon --
A. But on the previous page or the next page, I saw a list of solvents.
Q. Okay. Let's take a look at that.
MR. BERNARDO: Let's go to the next page.
A. Maybe it was the previous page, I don't

Page 170

know. I saw it. So, you know, they didn't want to have solvent residues in their -- in their API.
Q. Dr. Hecht, do you know what steps, if any, ZHP took in response to the issue that you're describing?
A. To the solvent residues?
Q. Yes.
A. I really don't remember.
Q. Do you know if they did --
A. They might have -- they might have done some analyses of the solvent residues that were mentioned, and I don't remember.
Q. Okay. So as you sit here today, you're not in a position to explain what the circumstances were, with respect to the fourth item on page 6 that you describe as "customer complaints." Is that fair?
MR. SLATER: Objection.
You can answer.
A. No, I wouldn't say that. I mean, there were definitely aberrant peaks in the chromatograms that they obtained when they analyzed the API, so I mean, that -- you know, that was a problem.
Q. Okay.
A. I can't say exactly what these peaks were, and I don't recall exactly what the resolution

Page 171

of the thing was. Because I think around that same time then, that's when Novartis discovered the NDMA, and that kind of made all this other stuff irrelevant. Because then, as ZHP had to go back and analyze their 5,000 batches, and they found NDMA in all of them. So I mean, that kind of made all these complaints totally irrelevant.
Q. Well, then, if you think these complaints are irrelevant, then I don't want to spend time going through them and understanding your knowledge, Dr. Hecht. But they're listed in your report, and I'm trying to understand why you listed them, the points that you're trying to make about them and the extent to which you rely on them. If they're irrelevant --
A. Because -- because --
MR. SLATER: One second, Doctor. Doctor.
Objection to the question. You've cherry-picked one thing without other parts. You haven't asked about the rest of the citation in that number, including the deposition testimony. The foundation is very misleading. You have his report.
You can answer the question.
A. They show a lack of care.

Page 172

Q. Okay. They show a lack of --
A. And that's -- that's pertinent to the big issue.
Q. Okay.
MR. BERNARDO: Let's pull up Tab 26. Or Document 26.
(Exhibit Hecht-16, Email Chain ending December 27, 2016, Bates ZHP0477534 through 477553, was received and marked for identification.)
Q. Okay. I'm showing you a document that I've marked as Exhibit 16, a December 27th, 2016, email from Sophie Lee to a variety of recipients.
A. Okay.
Q. Do you see that? And why don't we pull up -- this is another document that's in Chinese, so we will pull up the English translation that was provided.
MR. SLATER: I'm sorry, I totally got spaced. Did you say that you pulled up deposition testimony? Because I see a document.
MR. BERNARDO: No, I said I pulled up a document, Adam, and I identified the document for the record. And I'm about to ask him if he's seen it, but I want to pull up.
Or is that the English? Oh, sorry.

Page 173

Hold on a second.
Q. So Dr. Hecht, this is not --
MR. BERNARDO: Let's pull this back up.
Q. This is not a document --
MR. BERNARDO: Let's go back to the beginning, Josh.
Q. This is not a document that was listed in your report. Is it fair to say, therefore, that you did not see this document, or you don't have a recollection of having seen this document, in connection with the points that you were making on page 6 of your report?
A. I don't remember if I've seen this or not. Maybe I did, maybe I didn't.
Q. If you did, and you were using it to make your point, wouldn't you have listed it in connection with the fourth item, as being pertinent to that?
A. I don't know.
Q. You don't know whether you would have identified it? Okay. So --
A. I don't know. I don't see the relevance of this whole thing. So, you know, what are you trying to get at?
Q. If you go to page 4 of this document.

Page 174

Okay? We see a December 22nd, 2016, email. Right?
A. Yeah.
Q. Okay. In which Jenny Liu writes that, and why don't you -- yeah.
"It seems that your product cannot fully comply with ND for residual solvents before two to three years ago. Vertex claimed that there were additional peaks appeared which was not indicated in ND. So I'm worried if your product can fully comply with ND and if you can sign on it. Please recheck."
Do you see that?
A. Yeah.
Q. Okay. That's from Jenny Liu at Shanghai Pharmtech Company. Correct?
A. Yes.
Q. And who -- who is Shanghai Pharmtech Company?
A. It's one of their customers.
Q. Okay. And then, if you continue on, she says, "We haven't received any complaint."
So do you have any reason to dispute that this line of communication pertains to the same Vertex issue that we've been talking about, Dr. Hecht?
MR. SLATER: Objection. This entire

Page 175

line of questioning, it's just being --
A. What same Vertex issue?
MR. SLATER: Let me finish, Doctor. Doctor, let me finish.
The foundation for this whole entire line of questioning is completely misleading, and it's just completely inappropriate, the way this is being approached.
You can answer the questions as best you can. I'll clean it up later.
MR. BERNARDO: I'll give you a running objection on that.
MR. SLATER: I don't want a running objection to this, honestly, because I want to be able to place the objections as you go. Because what you're doing here, with the cherry-picking, is really, really misleading.
Q. Dr. Hecht, I'm showing you documents that you have not cited to, that pertain to the very same specific circumstances that, I will represent to you, Dr. Hecht, show the investigation that was done and the description of what those unknown peaks are.
I will tell you right now, that's what I'm trying to do here, through documents that you didn't look at. Your counsel is objecting, and you

Page 176

said that these show an absence of care.
And I'm trying to determine whether or not other documents that you did not look at, or do not appear to know about, or have seen, or don't remember having seen, have impacted that. I just want to explain to you what I'm doing, to make this a little bit simpler --
MR. SLATER: Yeah, I object to your colloquy; I object to everything else you're saying.
MR. BERNARDO: Okay.
Q. And it says, "Dear Jenny, we haven't received any complaint from other Russian clients for valsartan quality. If it's problem for Vertex, then we have to withdraw the signed ND."
Do you see that?
A. Yeah.
Q. Okay. And then Jenny Liu responds, and we'll look at that.
And it says, "Good morning. Last time you provided three batch samples of valsartan and I just asked the test results about the solvents. Here is the reply. Please comment. It seems there are many additional peaks which did not indicate in ND."
Do you know what the "ND" is?
A. No, what is "ND"?

Page 177

Q. That's what I'm asking, if you know what "ND" means.
A. What is this? Tell me what it is?
Q. Okay. So it's what is referred to as a normative document. Do you know the purpose of a normative document?
A. To -- it's a validation document for the material.
Q. Okay. So what they're saying is they found things which were not in the normative document. Correct?
A. Yes.
Q. Okay. And if you look at what is listed below, none of them are nitrosamines. Correct?
A. That is correct.
Q. Okay. And it says, "Please provide justification of appearances of these peaks." Correct?
A. Yep.
Q. Okay. So this communication is not about a complaint with respect to unknown peaks that were nitrosamines. Is that fair?
MR. SLATER: Objection.
You can answer.
A. What do you mean? What do you mean,

Page 178

"unknown peaks"?
Q. What they determined are that these are the peaks that they found. Correct?
A. This is what they found, right.
Q. Right. Okay. Do you know what ZHP did to investigate this, to come to this conclusion?
A. No. I mean, I'm not sure I understand your question.
Q. Okay. Did you know that -- and you have not read this; but did you understand, either through the testimony or through the document that we're looking at, that it was determined that Vertex wasn't actually using the right valsartan ND?
A. No. I don't -- I don't know.
Q. Okay.
MR. BERNARDO: Let's take a look at the document with the Bates number ending in 2709940, which we'll mark as Exhibit 17.
(Exhibit Hecht-17, Email Chain ending February 29, 2019, Bates ZHP02709940 through 2709984, was received and marked for identification.)
Q. Okay. And this is another email --
MR. BERNARDO: Go to the front page, okay.
Q. This is another email that's part of

Page 179

this chain. And if you go down to page 7, you can see -- you see the same chain that we just looked at, Dr. Hecht?
A. No.
Q. Okay. So you can see that this includes her last email about the peaks issue. Right?
A. Yeah.
Q. Okay. And this is another document that you do not cite in your report. Is that correct?
A. Right.
Q. Okay. And you would agree, if you look at it, this relates to the issue we've been discussing. Correct?
A. I would agree with what?
Q. You would agree that this particular email chain relates to the issue that we've just been discussing with respect to Vertex, that's cited on page 4 of your report. Correct?
MR. SLATER: Objection, foundation. You can answer.
A. I don't know. I suppose so.
Q. Well, I guess let me ask it a different way. Based upon the context and what is in this document, do you have any reason to disagree that this appears to relate to the same issue that we've

Page 180

been talking about?
A. No.
Q. Okay. If we go through, and we can scroll through the document, I want you to take a look. And you can see that ZHP worked with Jenny Liu and Shanghai Pharmtech to try and figure out what was going through with these peaks. And we'll scroll through. Okay?
So Dr. Hecht, do you have any disagreement that this document, which is a 45-page document -- and again, you're free to pull this up, and your counsel can send it to you at a break, and we thought we had technology that allowed you to do it. I just want to have you look at it.
This shows that they were looking at this from December 2016, into well into 2017. Do you have any reason to dispute that?
A. No.
Q. Okay. And if you look at the email at the bottom of page 3, it says that Vertex is not asking ZHP to remove the peaks, because Vertex already defined what the peaks were. Is that correct?
A. Yeah.
Q. Okay. They just wanted an explanation

Page 181

about the nature of the peaks. Right?
A. Yeah.
Q. And then there's some back-and-forth about the testing that was done by Vertex to find the peaks. Correct?
A. Yeah.
Q. Now, if you go to the top of the first page of the document, which would bring you to sort of the last-in-time email, ZHP responds that Vertex was using the wrong normative document.
Do you see that? It says -- and it gives a number, "Is not our valsartan ND number. Our valsartan ND number is," and then they provide -- they provide that. Do you see that?
A. Okay, yes.
Q. Okay? So ZHP says that the valsartan ND is actually different. Is that fair?
A. That's what they're saying.
Q. So there's clearly some confusion going on at Vertex, pertaining to this whole circumstance. Is that fair?
A. Yeah.
Q. And I raise this, Dr. Hecht -- and I'm not going to go through all of these. Is it fair to say, this is an example of how, if you look at other

Page 182

documents that provide context for the documents that you cite, they may provide additional explanation that's inconsistent with what might appear on the face of the document that you cite?

MR. SLATER: Objection.

You can answer.

A. I don't know what you're talking about.

Q. Well, having --

MR. SLATER: You're arguing with him. I mean --

MR. BERNARDO: I'm not.

MR. SLATER: It's not -- come on.

Q. Dr. Hecht, let me ask you a question. Having walked through this document, do you think this is an example of ZHP not caring, as you described, these are examples?

MR. SLATER: Objection.

You can answer.

A. Did I say that, not caring?

Q. That was your word, Dr. Hecht.

A. Yeah. No, sure, they -- they have to care about it. I mean, this is their product, so.

Q. So is it fair to say that -- again, and you're welcome to look at as much or as little of this as you want to to answer my questions, and

Page 183

you'll tell me if you need to look at more.

Do you agree that, based upon what I've tried to walk you through, that this demonstrates that ZHP took the customer complaints seriously?

MR. SLATER: Objection.

You can answer.

A. I don't know if they took the customer complaints seriously or not, really. I mean, yeah, this would indicate that they do. And they have to do that.

Q. Let me ask it a different way, because that's a fair point.

Does this demonstrate that they appropriately responded to an inquiry about unknown peaks?

MR. SLATER: Objection.

You can answer.

A. It seems to, yes.

Q. Okay. And it shows that the unknown peaks had nothing to do with nitrosamine development. Is that fair?

MR. SLATER: Objection.

You can answer.

A. I don't know about that. I mean, I don't want to answer that. I mean, you know, there

Page 184

were unknown peaks, and, you know, the nitrosamines were also in there. And --

Q. But the --

(Simultaneous speaking.)

MR. SLATER: I'm sorry, Mr. Bernardo, you're interrupting him.

A. By the time -- by the analyst. So I don't think I should answer that.

Q. Okay. But the unknown -- the unknown peaks turned out not to be nitrosamines. Correct?

MR. SLATER: Objection.

A. The ones they're listing here were not nitrosamines, but that doesn't mean that there were not nitrosamines in there.

Q. And I'm not --

A. So there might be other unknown peaks that they didn't even see, or they didn't mention or they didn't look at. So they were just probably looking at the bigger peaks.

So, you know, these solvent-related compounds are going to give larger peaks in the chromatograms than the ones of interest here, the nitrosamines. Nitrosamine peaks will be very small compared to these, by the -- by the method they're using. If that's what you're trying to get at.

Page 185

Q. I'm not trying to get at anything, Dr. Hecht, I'm simply trying to ask the question.

Now that we've been through at least some additional communications pertaining -- and to be clear, I'm not representing that this is the totality either. I'm just trying to show that this is an example of, there are additional communications.

But now that we've walked through this, do you think that this example should be on your list of examples that are pertinent to your opinion?

MR. SLATER: Objection.

You can answer.

A. I don't think this is pertinent to my opinion at all.

Q. Okay. And that's because --

A. I think it's irrelevant.

Q. Okay. Thank you, Dr. Hecht.

Let's take a look at another one, let's look at Number 5, and Number 5 is Glenmark.

Do you see that on your report, Dr. Hecht?

A. Yes, Glenmark.

Q. Okay. And have you look at the documents. So there are three documents cited with

Page 186

respect to Number 5. Do you see those?
A. Yes.
Q. Okay. And I take it you've looked at those documents?
A. Probably.
Q. Can you -- can you, as you sit here today, explain to me the circumstances with Glenmark, such that it's an example of one of the customer complaints you're pointing to in your report?
A. No, I don't remember --
MR. SLATER: Do you want him to give the --
A. I don't remember the details.
MR. SLATER: I'm sorry. Do you want to give him the documents and the deposition testimony that's cited in the report?
MR. BERNARDO: I want to ask him questions without being interrupted, but I don't think that's going to happen.
Q. So as you sit here today, you're not recalling, Dr. Hecht? Is that fair?
MR. SLATER: Objection.
Q. I just want to understand, as you sit here today, what you can tell me, without looking at documents. That's all I'm trying to get at. If it's

Page 187

nothing, it's nothing. That's fine.
MR. SLATER: Yeah, objection.
You can answer.
A. I don't remember the specifics of this document.
Q. Okay.
MR. BERNARDO: Let's pull up the first document that's cited.
MR. SLATER: Well, first -- are you talking about under Glenmark in the report? The first document cited was deposition testimony. So I assume you're going to the second document cited, which is not the deposition testimony?
MR. BERNARDO: I'm referring to documents, separate and distinct from testimony.
MR. SLATER: Right.
Q. Okay. And let me ask, since Mr. Slater raised that. Do you recall anything, or can you point to anything in testimony with respect to the first document -- or the first circumstance we did with respect to Vertex, that would somehow change your opinion, having now looked at the underlying documents?
MR. SLATER: Is the question without looking at the testimony?

Page 188

A. My opinion will not change.
Q. Thank you.
A. I don't care what you bring up.
Q. Okay.
A. My opinion is solid.
(Exhibit Hecht-18, Email Chain in Chinese Language ending February 28, 2019 previously marked ZHP-271, Bates ZHP00496153 through 496154, was received and marked for identification.)
Q. The first document you cite that is not testimony is ZHP-271. And this looks like it's in English. And again, there's nothing -- do you want to flip through the document? There's nothing of substance; this is just a cover transmittal. Is that fair?
A. Yes.
Q. Okay. Let's bring up the second one, which is ZHP-272.
(Exhibit Hecht-19, Document in Chinese Language previously marked ZHP-272, Bates ZHP00496155 through 496156, was received and marked for identification.)
Q. And that one is in Chinese, so we're going to bring up 272A, which is in English.
(Exhibit Hecht-20, English Translation

Page 189

of Hecht-19, previously marked ZHP-272A, was received and marked for identification.)
MR. BERNARDO: I'm sorry. Thank you.
MR. SLATER: By the way, Mr. Bernardo, I think, but I could be wrong, because I wasn't in this deposition. But my understanding is Mr. Lee was deposed about the Chinese documents, and the English translations were given to counsel. I could be wrong; but you -- I just want to make that clear. You could probably look at the testimony to figure that out.
MR. BERNARDO: You very well may be right, and you can certainly make that point.
I'm simply trying to understand the extent to which Dr. Hecht has looked at these materials.
BY MR. BERNARDO:
Q. So can you -- so this is a three-page document. If we just take a minute and scroll through, can you explain to me what this is, and how it impacts your opinion? With respect to the 2016 complaint in December, from Glenmark?
A. I can't read that fast, sorry.
Q. No, no, no.
A. So, you know, apparently, there's some

Page 190

solvent peaks similar to the other one.
Q. Okay. So is there anything you can tell us about this document that's somehow relevant to your inclusion of the Glenmark customer complaint, and what you -- what, if anything, you derive from it?
A. I can't derive much from this document.
Q. Okay.
MR. BERNARDO: Let's look at the third and last document, which is Tab 34. What number is that?
MR. SCHOCH: Twenty-one.
MR. BERNARDO: Which is Exhibit 21. And how many pages is that?
(Exhibit Hecht-21, Email Chain ending December 22, 2016, Bates ZHP02118712 through 2118731, was received and marked for identification.)
Q. Okay. And this is, again, a much longer document, right? And it's from Francis D'Souza to a number of individuals.
Do you know who Francis D'Souza is?
A. I do not.
Q. Okay. And here, Francis D'Souza is identifying some unknown peaks, and asking ZHP for their justification and origin.

Page 191

A. Right.
Q. Is that fair?
A. Same deal.
Q. Right. If you go to the third page of this email chain.
MR. BERNARDO: Sorry, scroll back a little, there we go.
Q. There appears to be a preliminary analysis, some of Glenmark's preliminary analysis of what the peaks are. Do you see that?
A. Yes.
Q. Okay. So they aren't totally unknown. Correct? There's some at least initial analysis of what these peaks are. Is that correct?
A. Right, right.
Q. And Glenmark is really asking ZHP to confirm their identities and justify the origin. Correct?
A. Yep.
Q. Okay. And then ZHP responds on December 22nd, do you see that, saying they're investigating, and asking for the chromatograph for further investigation.
A. Yep.
Q. Right?

Page 192

A. Right.
Q. And then on December 22nd, Francis D'Souza responds with some more questions. Do you see those?
A. Yep.
Q. Okay. And if we go back to what we just looked at, that was Exhibit 20, that's -- was marked 278, that's the summary of communications between ZHP and Glenmark about the unknown peak. Is that fair?
A. Yes.
Q. Okay. And you can see the first communication that's up there on the upper left is December 19, 2016. That's the email we just looked at. Right?
A. Yeah.
Q. And then there's some responses from ZHP and Glenmark on December 22nd, 2016, and that's in the summary, you'll see those?
A. Yeah.
Q. Okay. Those are the ones that we just looked at. Then the summary goes on with communications back and forth for another couple of pages. Right?
A. Yes.
Q. Okay. It goes all the way until April,

Page 193

2017. Is that correct?
A. Yes.
Q. Okay. That's the last entry, and it says ZHP responded to Glenmark about Glenmark's replies. Right? And "there was no further feedback from subsequent customer and there's no follow-up." Do you see that?
A. Yep.
MR. BERNARDO: Let's take a look at the April 20, 2017, communication.
(Exhibit Hecht-22, Email Chain ending April 20, 2017, Bates ZHP02118680 through 2118708, was received and marked for identification.)
Q. And again, this was not listed in your materials, so I take it this is not something that you looked at, or you just don't know?
MR. SLATER: What exhibit number is this?
MR. BERNARDO: 22.
MR. SLATER: Exhibit 22. And what is it, it's an April 20, 2017 email?
MR. BERNARDO: Yes.
A. Yeah.
Q. Okay. And it has the same subject line: "Unknown peaks of residual" -- or attachments.

Page 194

A. Right.
Q. Okay. So it's no question but that it relates to the issue we've been talking about?
MR. SLATER: Objection.
A. I don't really agree with that.
Q. Okay. Fair enough. It appears to relate, from the text of this, and the description --
A. I don't know if it really relates.
Q. Okay. Let's go through the email -- I don't want to go through each page, and you'll see that ZHP and Glenmark are talking about these peaks.
MR. BERNARDO: Is the attachment part of this, Josh?
MR. SCHOCH: Yeah.
MR. BERNARDO: Okay.
Q. Do you agree that -- and you'll see this particular one, this is the one we just looked at a minute ago. They're talking about the three unknown peaks. Correct?
A. Yes.
Q. And this email has an attachment?
MR. BERNARDO: Let's bring that up, which is 23.
MR. SLATER: Are we still on Exhibit 22?
MR. BERNARDO: We're moving to

Page 195

Exhibit 23.
(Exhibit Hecht-23, Chart titled "D5191-15-359," Bates ZHP02118709 through 2118711, was received and marked for identification.)
MR. SLATER: 23, okay.
Q. And the attachment -- and this is an attachment from April 20, 2017. And the attachment actually lists all of the peaks that Glenmark raised. Correct?
MR. SLATER: Objection.
A. Yep.
Q. Okay. And you can see it identifies each of the peaks in the one, two, three, four, fifth column?
MR. SCHOCH: Page 6.
MR. BERNARDO: Under "Library Search," do you see that?
A. Yes.
Q. And none of those is nitrosamines. Is that correct?
A. Yes.
Q. Okay. And the table also includes the -- see that column that's highlighted in yellow and blue, that says "Origin of Impurities"?
A. Yep.

Page 196

Q. Okay. And the control mechanism for the impurities. Is that correct?
A. Yes.
Q. And then the limitation standard for those impurities?
A. Right.
Q. Okay. And this is the last communication in the summary correspondence, and Glenmark actually identifies each of the unknown peaks, and gives more information about each peak. Is that fair?
A. Yep.
Q. And again, these are not nitrosamines. Right?
A. Right.
Q. Okay. So looking at again, all of the communications -- and I'm not representing this is the entirety; I'm just saying these are more than what was listed in your report or listed in your reliance materials -- you would agree, wouldn't you, that it shows that ZHP was working with its customer to address and understand the origin of unknown peaks?
MR. SLATER: Objection.
You can answer.

Page 197

A. It appears that way, yes.
Q. Okay. Would you therefore take this off of your list of examples of the customer complaints that are relevant to your opinion on page 6?
MR. SLATER: Objection.
A. No, I would not.
Q. Why not?
A. Well, because, you know, these are instances of impurities being found in the -- in the API that these companies were purchasing from ZHP, so naturally, it's a concern.
Q. Is it a concern if they're within the limitation standard?
MR. SLATER: Objection.
You can answer.
A. When you see the peaks, the first thing you have to do is identify them, and then the second thing you have to do is quantify them. And then when that work is complete, then you can decide, you know, whether it's a problem or not.
Q. And is it fair to say, from the communications we just looked at, that that's in fact what happened: They were both investigated and quantified?
A. Well, it seems to be -- that, you know,

Page 198

that appears to be the intent.
Q. Okay. On page 7 of your report, on the top page, you'll see another customer complaint, Number 7. And it's Novartis, and that's the one in which nitrosamines or NDMA was identified. Is that correct?
A. Yes.
Q. Okay. In your report, you say --
MR. BERNARDO: You want to pull it down, just a little further.
Q. I'm in the third line, Dr. Hecht, beginning "Novartis."
"Novartis investigated the unknown peaks to determine what was causing them, and identified the NDMA in ZHP API manufactured with the zinc chloride process."
What do you mean when you say, Novartis investigated and identified NDMA?
A. How could it be clearer than that?
Q. Well, how about this. Let me ask --
A. They investigated, and they identified it.
Q. Okay. Walk me through the steps that Novartis took. And was it Novartis, was it a third party, when did it occur? I just want to

Page 199

understand --
A. As far as I know, it was Novartis in Ireland, someone named Kevin O' Mahoney, or something like that, that, you know, first suspected, and then figured out that it was NDMA.
And as far as I remember, that person took a look at the process that ZHP was using, and that gave him the hint that this -- that there could be NDMA in there. And then, and then he, they, confirmed it, Novartis confirmed it.
I believe that's the sequence of events. But, you know, I could be a little bit off.
Q. Okay.
A. Novartis went into a little more detail, I believe. You know, they actually looked at the process and, you know, they figured out that -- what could be going on here, because of the use of nitrite.
Q. Okay.
A. That's my understanding of it.
Q. And how did you get that understanding?
A. By reading. Reading the reports, reading the binders and everything.
Q. So you're saying the binders contain information that delineate the steps that Novartis

Page 200

took?
A. I don't know. I read it, okay? I didn't make it up. It's in the material that I have.
Q. I'm not suggesting you made it up, I'm just trying to understand, so I can --
A. Yeah.
Q. -- see how --
MR. SLATER: Objection to form.
A. It's in the -- it's in one of the binders. I have the -- I have something from Novartis, from this guy, Kevin O'Mahoney in Ireland, that, you know, identified the NDMA.
And I don't think the document that I have actually goes into the origin of it, but he figured it out. And the reason he was able to figure it out was, I'm sure, although I don't know if it's in the documents, is that he looked at the process. And once you look at the process, then you're going to figure it out.
Q. So you just said you're sure, but you don't know if it's in the documents. If it's not in the documents, how else would you be sure that they looked at the --
A. Okay, I don't know that. Maybe I'm not sure.

Page 201

Q. Okay. Again, I'm just trying to understand. So --
A. I read this, I definitely read that Novartis figured it out. And as far as I know, it was by someone named Kevin O'Mahoney. And that's -- somewhere in -- somewhere in these binders is that. I can't remember exactly where it is.
Q. Do you know --
A. But I couldn't make something like that up.
Q. I'm not suggesting you did, Dr. Hecht.
Do you know if Novartis did the testing themselves, or if they retained a third party to do the testing?
A. I don't remember.
Q. Okay. Do you know if Novartis conducted any other tests previously to this, and the results of those tests?
A. I don't -- I don't know. I don't remember how much Novartis did.
Q. Okay. Do you know the circumstance of why Novartis was testing?
A. Yes.
Q. What were they?
A. They looked at the procedure.

Page 202

Q. Why were they looking --
A. And they saw -- I mean, how many times do I have to repeat it? They saw how they decomposed the sodium azide by dumping in nitrite at pH [redacted] in the presence of the product. And then the light bulb went off.
Q. Do you know how long Novartis, if they were, were testing API from ZHP?
A. No, I don't know how long.
Q. Okay. And as we just identified before, you will agree that sometimes additional documents or additional communications can shed more light on communication that you're looking at. Correct?
MR. SLATER: Objection.
You can answer.
A. Sure. The more information we have, the better off we'll be. I don't know what your point is.
Q. You answered my question. That was my only point.
A. All right.
Q. Do you know whether Novartis did any testing of valsartan, prior to May of 2018?
A. Not that I'm aware of.
Q. But you don't know, one way or the other?

Page 203

A. No, I don't know.
Q. Do you have any reason to dispute that Novartis conducted testing on valsartan API, prior to 2018?
A. I don't know.
Q. Okay. Hypothetically --
A. I don't know whether they did or they didn't. That's my answer.
Q. Hypothetically -- understood. Hypothetically, if Novartis did conduct testing on valsartan API prior to May 2018, and did not find NDMA, would that factor into your consideration and the forming of your opinion?
A. No, because in order to find NDMA in the testing, you need to be looking for it. All right? The peaks -- the NDMA peak would be too small for it to stand out. That's why some of these companies missed it, because they looked at the solvents, the ones we were just talking about. They're going to be like relatively larger peaks. The NDMA peak is going to be very small.
So you wouldn't see it. You wouldn't notice it unless you were actually looking for it. And that's why only Novartis figured it out, because

Page 204

the guy at Novartis was smart enough to look at the procedure, and he saw how ZHP dumped in nitrite at pH [redacted] and then he said, well, there might be nitrosamines here, so let's look at NDMA. That's what happened.
Q. I want to shift gears to -- and if we turn to your report --
MR. SLATER: If we're going to a different area, now would probably be a good time to eat.
MR. BERNARDO: No, I'm thinking -- yeah, right. I was going to say, I could do this pretty quickly. Why don't we do that, Adam.
MR. SLATER: I mean, now it's late enough.
MR. BERNARDO: Yeah, yeah.
MR. SLATER: How much time does everybody want to take?
THE VIDEOGRAPHER: Should we go off the record first, Counsel?
MR. BERNARDO: Sure, please.
THE VIDEOGRAPHER: Going off the record. The time is 12:45 Central Time. This is the end of Media Unit Number 4.
(A luncheon recess takes place.)

Page 205

THE VIDEOGRAPHER: We're back on the record. The time is 1:27 p.m. Central Time. This is the beginning of Media Unit 5.
CONTINUED EXAMINATION BY MR. BERNARDO:
Q. Good afternoon -- yeah, it's afternoon in Minnesota, yes. Good afternoon, Dr. Hecht. We've had a little lunch break here.
I want to go back to further discuss a topic we talked about this morning, the decomposition of DMF. And again, for purposes of these questions, Dr. Hecht, I want to clarify: I understand your opinion that there may have been dimethylamine in DMF already, but I want to assume there was not. I want to assume that whatever contribution of DMF came through degradation, for purposes of these questions.
Do you understand what I'm saying?
A. Yes.
Q. Okay. So if the DMF degraded to form dimethylamine, it's my understanding from your earlier testimony that it's your opinion that that occurred when the process was heated to [redacted] degrees celsius. Is that correct?
A. Yes.
Q. Okay. Is there any other point in the process you believe that if degradation was what

Page 206

resulted in the formation of dimethylamine, that that would have occurred?
A. This was -- this would be the most likely.
Q. Okay. Well, you say "it would be the most likely." I just -- I just want to understand, so we can talk about others, if there are others.
A. I don't have any others in mind.
Q. Okay.
MR. BERNARDO: I want to pull up -- I don't think we've marked it already, have we, Josh?
Q. Okay. One of the publications you cite to -- and I'm not sure exactly how to pronounce it, so I'll just call it Armarego, if that is right.
MR. BERNARDO: And let's mark that as exhibit -- what are we up to? 24.
(Exhibit Hecht-24, Excerpt from Purification of Laboratory Chemicals, Fourth Edition, by W.L.F. Amarego and D.D. Perrin, No Bates, 21 Pages, was received and marked for identification.)
MR. SLATER: Doctor, if you have that there, you can pull up the hard copy too, if you need to.
Q. And before we get into -- so this is -- what I've marked as Exhibit 24 is a book called

Page 207

Purification of Laboratory Chemicals, Fourth Edition.
And you're familiar with this book. Correct, Dr. Hecht?
A. Right.
Q. When did you first become familiar with this publication?
A. Oh, this is like a standard in the -- you know, there's a whole shelf full of standard kind of laboratory -- not manuals, exactly, but different books that collect laboratory methods that are, you know, relevant to those that are commonly used in organic chemistry laboratories. So, you know, this is one of those.
Q. When did you first -- do you have a copy of this?
A. I do not.
Q. Okay. When is the first time that you saw this?
A. Probably about 40 years ago. I don't know; I don't remember.
Q. What would be the circumstances for which you would consult this type of publication?
A. Well, if we're doing a process in the lab, and, you know, we had to use a solvent or reagent that we hadn't used before, and, you know, we

Page 208

want to find out more about it. So in the lab, we would have, you know, bookshelves -- or not in the lab, necessarily, but, you know, in the area, where -- like a reference library. And you know, you would go to a book like this to find out more about a particular solvent or process that you were using. These kinds of books are very useful.
Now they're probably all online. But in the past, it would be typical to have, you know, bookshelves with relevant references available.
MR. BERNARDO: If we can go to the preface of this. Okay. And if you go down to -- Josh, if you can find that, "to keep this book in a convenient size, portions." Josh? Oh.
Q. Okay. This -- and we'll undo it, because I know this makes it harder for you to look, but I just wanted to point out to you where I'm looking.
It says, "To keep this book a convenient size, and bearing in mind that its most likely users will be laboratory trained, we've omitted manipulative details with which they can be assumed to be familiar, and also detailed theoretical discussions."
Do you see what I just read?

Page 209

A. Yes.
Q. So this book is not intended to communicate information with which a lab technician would be assumed to be familiar; they omitted that, to help the size of the book. Is that a fair interpretation of what's being said there?
MR. SLATER: Objection.
You can answer.
A. Well, yeah, I mean, that's what it says. But, you know, that's a matter of opinion, obviously. So, you know, what to include and what not to include. You don't know what a person's likely to be familiar with or not. I mean, it's all a matter of opinion.
Q. Of course, it is. But it's the opinion of the authors and people who had responsibility for this book, that this book only includes things with which people would not be expected to be familiar. That's what they're saying here. Is that fair?
MR. SLATER: Objection.
You can answer.
A. Probably.
Q. Okay. And if you go back to the preface to the fourth edition -- or go to the preface to the fourth edition. It says on the bottom, you see it,

Page 210

there's a total of --
MR. SLATER: Wait, I'm sorry, Rich. Is this a different edition? Because that was the preface, I might have just blanked it?
MR. BERNARDO: No, we're in the same -- the same edition that I've been showing him, and this is the same thing that's been cited, as far as I'm aware. I haven't left the same book.
MR. SLATER: Got it. Got it. It confused me, because it looked like there were two prefaces.
Q. The authors point out that there's a total of 5,700 entries. Correct?
A. That's what it says.
Q. And this book is -- if I'm correct, Dr. Hecht, it's not a textbook; it's a compendium, listed alphabetically, of various chemical -- I don't know whether they're called compounds, or -- but there's -- it's almost like -- a little bit more of an encyclopedia. Is that fair?
A. Yeah, you could say that.
Q. Okay. And is it also fair to say that you wouldn't expect that any lab chemist would commonly know every one of the 5700 entries in this book? Can you agree with that?

Page 211

I think we agree from your response, but I'd like you to confirm?
A. Probably.
Q. In fact, you don't know if -- I would assume -- every one of the 5700 entries in here, and what they say?
A. That's a good chance that's correct.
Q. So the fact that it is in this book does not mean that information about the conditions under which DMF could degrade would be widely known. Is that fair?
MR. SLATER: Objection.
A. Well, you know, if I were making kilograms of valsartan, I would certainly check into every reagent that's being used in that process. Absolutely. This not like a casual experiment, you know, that you do, "oh, let's try this and see if it works." You know, this is an industrial process where the materials are going to be distributed worldwide.
So I would make damn sure that everything that I used, everything that I did in this process, was bulletproof.
MR. BERNARDO: Ellen --
A. So yeah, I would look at it.

Page 212

MR. BERNARDO: Would you read back the question?
Q. Because I don't think that's the question I asked, Dr. Hecht?
(The testimony is read back.)
MR. SLATER: Objection.
You can answer.
A. It may or may not be widely known. I was certainly aware of it.
Q. Okay. Fair --
A. I don't know whether it's widely known or not. But I repeat: If I were doing this on the scale that they're doing it, I would certainly look into it.
Q. And Dr. Hecht, and I -- we've done a search; I mean, you've written several hundred articles. Is that fair to say?
A. Yes.
Q. We didn't find any citation of this portion of this publication discussing degradation of DMF in any of your writings. Is that consistent with your expectation?
A. I'm surprised you went through all of them, but --
Q. We didn't read them all, but that's what

Page 213

computers are for.
A. I don't -- I don't think we used DMF that much.
Q. Okay.
A. In the studies we did. But I was certainly familiar with the fact that DMF, you know, could have dimethylamine in it, or could be hydrolyzed into dimethylamine. I mean, that's like basic chemistry.
Q. And again, I just want to understand this book.
MR. BERNARDO: If you can go back to the first page again, Josh, please.
Q. You would agree, this is not what you would characterize as a textbook; it's not something that would be used to teach organic chemistry or chemistry. Is that fair?
MR. SLATER: Objection.
You can answer.
A. Well, that depends. I mean, if you're teaching a laboratory course, you might very well use this book.
Q. Okay. Do you know whether anybody teaching a lab report -- laboratory course does use this book?

Page 214

A. I have no idea.
Q. Okay. And again, it's talking about "Purification of Laboratory Chemicals." If you're purchasing -- like if you're using DMF that you purchased, and if you took steps to -- or your quality steps ensure that it didn't contain dimethylene -- dimethylamine, would there be any reason for you to consult this purification of DMF -- consult this purification manual to determine how to purify DMF?
Let me -- and that was a bad question, Dr. Hecht, I'm sorry.
I want you to assume the following. I want you to assume that a manufacturer uses DMF that's purchased, and that it's purchased pursuant to specifications to ensure its purity. If that were the case, would there be a reason for somebody to look up how to purify, or the purification of DMF, in this particular book that we're looking at here?
MR. SLATER: Objection.
You can answer.
A. No, I mean, you know, if the -- if the standards were given by the person selling it -- by the company selling it, you know, and dimethylamine was one of those standards, I don't think there would

Page 215

be a reason to necessarily look into it.
But -- you know, again, I would certainly -- well, if I were using the process that they were using, I would have checked to make sure there's no dimethylamine; either in the DMF to begin with, or that's not formed during the process.
Q. What would you have checked --
A. That's my bottom line.
Q. Understood. What would you have checked?
MR. SLATER: Objection.
You can answer.
A. I would check the DMF for dimethylamine. That's easy to do by GC-MS.
Q. Okay.
A. Or I would also look into the formation of dimethylamine, under the conditions that I was doing the synthesis.
Q. Thank you.
MR. BERNARDO: Let's turn to page, is it 192, yes. Can you make that a little bit bigger? That's good.
Q. And this is the paragraph of this book that we've been looking at that's relevant to your testimony. Is that fair, the one that's on the

Page 216

screen?
A. Yes.
Q. Okay. Thank you. And it says -- what are the various abbreviations up front, the M, the B, the 153 degrees, what does that all mean?
A. The M is the molecular weight --
(Court Reporter Clarification.)
A. Molecular weight. B is the boiling point, at two different pressures. D is the density, and N25 is the refractive index, I believe.
Q. When you say it's two different pressures, give me a little bit more understanding of what you mean by that, with respect to the boiling point?
A. Well, boiling point is a function of pressure. So, you know, if you go on a camping trip and you go up to the top of a mountain and boil your water, you'll find that it's not a hundred degrees; it's less. So as the pressure goes down, so does the boiling point.
Q. And what does the 153 degrees represent there, with respect to pressure?
A. So 153 is the boiling point at atmospheric pressure, 760 millimeters.
Q. And then what's the 76 degrees; what

Page 217

pressure is that?
A. 39 millimeters of mercury.
Q. And what would have been the conditions and pressure at the step in the valsartan manufacturing process where you say that DMF could have degraded?
A. That would be the 153.
Q. Okay. So --
A. I mean, the pressure would be the 760.
Q. Thank you. I understood what you meant, but thank you for that clarification.
So it says here that -- can I just refer to it as "DMF"?
"DMF decomposes slightly at its normally boiling point" -- and that, we just discussed, was 153 degrees celsius. Correct? You're nodding, but please --
A. Yes.
Q. Thank you.
"To give small amounts of dimethylamine and carbon monoxide."
But I thought we just talked about the temperature when heated in the valsartan manufacturing process was [redacted] degrees celsius. Correct?

Page 218

A. For [redacted] hours.
Q. Understood.
A. For [redacted] hours.
Q. Understood. Let me ask my question, then. I just want to make -- we agree that for -- put aside the time; we'll talk about that in a minute. It was not for [redacted] hours maintained at a boiling point, or even reaching a boiling point; it was many degrees lower than a boiling point. Is that fair?
MR. SLATER: Objection.
You can answer.
A. [redacted] degrees lower.
Q. [redacted] degrees celsius lower?
A. Correct.
Q. Which is about -- I'm really bad at this, about [redacted] degrees Fahrenheit lower?
A. That's about right, yep.
Q. Okay. So sort of the difference between, you know, [redacted] degrees and [redacted] degrees Fahrenheit, just for a reference point. Is that right?
A. Yep.
Q. Okay. Does it say anyplace in here that the duration of time at a lower boiling point could

Page 219

increase the risk of degradation to form dimethylamine?
A. No, it doesn't go into that, but I can tell you from experience that it -- you're going to get some dimethylamine, if you heat DMF at [redacted] degrees for [redacted] hours. You're going to get some dimethylamine.
Q. And you say from -- I think you said from experience. Tell me what experience you have at heating dimethylamine at [redacted] degrees celsius for [redacted] hours, or some --
A. You mean heating dimethylformamide.
Q. Sorry. Heating DMF. Sorry. Let me --
A. No, I don't have specific experience with dimethylformamide that I can recall, but I have lots of experience with organic chemistry and organic synthesis. And, you know, just because the -- this difference between 153 versus [redacted] degrees, especially given the timeframe of [redacted] hours; I can guarantee you that some dimethylamine is going to be formed. I'd stand by it.
Q. I appreciate that you stand by it. And I'm trying to just understand why you do, and how you do. I'm not trying to challenge you, Dr. Hecht; I'm just trying to understand.

Page 220

So your standing by that is not based upon your experience of heating DMF to [redacted] degrees for [redacted] hours -- [redacted] hours. Correct?
A. Not specifically with DMF, but it is based on my experience with organic chemical reactions. And I can guarantee you, a hundred percent, that some dimethylamine will be formed if you heat dimethylformamide for the length of time they said in the thing -- I just blanked on. But you're going to get some.
Q. Okay. But again --
A. Because that's how organic chemistry is. Okay? It's not -- so I disagree with the other -- with the guy, Xue, on this. I mean, he goes into that in his report, but I think he's wrong there. I disagree with that.
Q. Understood.
A. Because he says specifically that no, we didn't heat it to 153; we only heated it -- they only heated it to [redacted].
When I read that, I thought to myself, is he kidding? I mean, that's not enough of a difference. Okay? You're going to get some dimethylamine. And they proved that by finding dimethylnitrosamine when they added nitrite.

Page 221

Q. What did they prove? Wasn't the dimethylamine already formed when they added the nitrite, in your opinion?
MR. SLATER: Objection, mischaracterization.
You can answer.
A. I'm not sure what you're asking. But I do know that when they added nitrite and they got dimethylnitrosamine, which everybody agrees happened, that that demonstrates that there was dimethylamine in there. Because that's one way you identify secondary amines: By making the nitrosamine.
Q. And I'm not questioning you as to what did or didn't actually happen. What I'm questioning you about is the knowledge that somebody might have.
And nothing in what we're looking at on the screen here, which is the purifications book that we've been talking about, says that if you heat it to [redacted] centigrade for [redacted] hours, it will degrade. Is that fair?
MR. SLATER: Objection.
You can answer again.
A. That's fair. But listen; this is a professional outfit that is producing materials by organic synthesis, okay? They know this. All right?

Page 222

What they didn't know, what they were non-aware of, was that formation of nitrosamine under their conditions would even be a problem. They never thought about that.

Q. Dr. Hecht --

A. That, that is where they fell down.

Q. The process --

A. I mean, they're oblivious.

Q. The process that we've been talking about of NDMA formation during the zinc chloride process, I want to talk about that a little bit.

Would you agree that there are multiple steps that have to occur in the NDMA formation process following the formation of dimethylamine from DMF?

A. Well, there's basically one step. I don't know multiple steps.

So you have nitrite in there; you're at pH[redacted]. So what happens is that you form N203, and N203 reacts with the amine to get the nitrosamine.

Q. Thank you. You saved me a lot of questions. That's what I was really trying to get at: Were the steps that was necessary for it to form, and you just explained them. Thank you.

A. It's a simple reaction, okay? It's not

Page 223

complicated. It's one of the simplest reactions in chemistry. That's why there's so much concern about it, and that's why there's so much contamination of various items. Because it's a very simple reaction, not complicated.

Q. I'd like to, Dr. Hecht -- and we can talk with you after the deposition to figure out the best way to coordinate that, mark the binders that you've got with you in your office?

MR. SLATER: You have them. Rich, you have them.

Oh, didn't you send them all to him already? Oh, we can -- I thought that they were already sent to you. We can electronically send them to you right now.

MR. BERNARDO: Sure. I just -- Adam, and we can discuss this after the deposition, I simply just want to have them be part of the record, so we have like an understanding on the record of exactly what they are. So I just want to mark -- I'm going to reserve --

MR. SLATER: Oh, so you don't want us to send them to you electronically so you can actually mark them? Because everything he was sent, we have electronically --

Page 224

MR. BERNARDO: Yeah, we can -- I want to discuss this --

MR. SLATER: Let me finish. Let me finish. It's a PDF with the index. Do you want to put a sticker on them? I have no idea -- and then what do you want to do, send them out to have someone --

MR. SCHOCH: Each binder is a separate PDF.

MR. SLATER: Yes, each binder is a separate PDF. We can send them to you; but if you don't trust us and you want to have stickers put on the binders, we can do that too.

MR. BERNARDO: This isn't a lack of trust or not, and we can talk at a break as to how to do it; I just want to have the inventory of what's in there be part of the record, and we can discuss the best logistical way to do that at a break. We don't need to --

MR. SLATER: I'm just offering you that we have PDFs of every single binder that we can just give to you, and then you can just mark them as exhibits and attach them right now.

MR. BERNARDO: Perfect. I don't want to go through that right now. We don't need to do that

Page 225

right now.

And I'm just going to reserve -- and we'll do it as one composite exhibit that we can just call Exhibit 25, which are the binders that Dr. Hecht has.

And I will accept Mr. Slater's representation that the copy he provides will be the copy -- or identical to the copy that Mr. -- that Dr. Hecht has.

(Exhibit Hecht-25, Composite Exhibit, Copies of Dr. Hecht's Exhibit Binders, was received and marked for identification.)

BY MR. BERNARDO:

Q. I want to talk about another topic, Dr. Hecht. And I want to go back to your report at pages 7 to 8.

A. Which one?

Q. I'm sorry, the October -- the October 31st, 2022, report, and I want you to turn to page 7 to 8.

A. Okay.

Q. There we go. My colleague just highlighted, and we'll take it off; I just want to draw your attention to the section that I'm pointing out, which is, "Of note, and perhaps not a

Page 226

coincidence, the July 27, 2017, email written by Jinsheng Lin, Ph.D. confirming that there was NDMA in ZHP's valsartan API caused by the quenching with sodium nitrite was written during the same month."

Do you see that?

A. Yep.

Q. Have you reviewed that email, Dr. Hecht?

A. Pardon me?

Q. Have you reviewed that email?

A. Yes.

Q. Okay. And I take it that was part of the materials that you were sent to review. Correct?

A. Yes.

Q. And the version that was sent to you was in English. Is that correct?

A. No, it was in Chinese.

Right.

Q. I'm simply asking, Dr. Hecht --

A. Okay. Yeah, it was in English.

Q. Okay. I understand you know this and I know this, but we just need to make things clear on the record. That's why I'm asking you this.

A. Okay.

Q. And you know that the document was originally written in Chinese. Correct?

Page 227

A. Yes.

Q. Okay. And it was produced in the litigation also in Chinese, as it was maintained in the ordinary course of business. Is that correct?

A. I guess so, yeah.

Q. Okay. And I think we established that you don't speak or read Chinese. Correct?

A. Correct.

Q. And are you aware that there are different English translations of this e-mail?

MR. SLATER: Objection.

You can answer.

A. No.

Q. Okay. Do you know -- and you've read one translation. Correct?

A. Yes.

Q. Okay. And obviously, you would not understand the original Chinese if you read it. Fair?

A. That's fair to say.

Q. So you relied on the English translation that was provided to you. Fair?

A. I did.

Q. Okay. Do you agree that you, sitting here, have no way of knowing if that translation is

Page 228

actually accurately translating what was said in Chinese?

MR. SLATER: Objection.

A. I have some Chinese colleagues in my lab. I could easily find out.

Q. I'm not asking you if you could find out; I'm asking if you've done that?

MR. SLATER: Objection.

You can answer.

A. I have not.

Q. Okay. And we know already that you've read Dr. Xue's export report. Correct?

A. Yes.

Q. And in his report, he addresses this email. Do you recall that?

A. Yes.

Q. Okay. And, you know, I think, because he says it, that Dr. Xue is a native Chinese speaker. Correct?

A. Yes.

Q. And he obviously also speaks English. Correct?

A. Yes.

Q. And he's also a chemist. Correct?

A. Right.

Page 229

Q. So fair to say, he's probably in the best position to understand what is said in here, because he has both native Chinese speaking skills, and a deep understanding of chemistry?

MR. SLATER: Objection. Compared to who?

A. Yeah, I don't know about that.

Q. A better understanding --

A. First of all, I don't know -- I don't know anything about his Chinese skills, even though he says it's his native language. You know, there are different dialects and stuff. So I really don't know. I have no idea.

Q. Okay. It's fair to say --

A. His chemistry, I think, is probably pretty strong.

Q. Okay. Fair to say that minor distinctions in wording, in science in particular, can result in different meanings?

MR. SLATER: Objection.

A. It's possible.

Q. Okay. And do you have any reason, as you sit here today, to dispute his conclusion that when you read the document in its original Chinese, the email makes no reference to possible nitrosamine

Page 230

formation, from the TEA process with quenching or the zinc chloride process, for valsartan API?
MR. SLATER: Objection.
A. Well, the email talks about nitrosamine formation.
Q. I'm asking if you have any reason to challenge or dispute his conclusion that it makes no reference, when you read the original Chinese, to possible nitrosamine formation from the TEA process with quenching, or the zinc chloride process for valsartan?
MR. SLATER: Objection.
You can answer.
A. I haven't tried to read it in Chinese, so I have no idea.
Q. So that's -- you don't have, as you sit here today, a basis to dispute that. Is that fair?
MR. SLATER: Objection.
You can answer.
A. What I have is an English translation. Okay? So, you know, the person who translated it maybe didn't translate it correctly, it's possible. But I have an English translation. I didn't look at the memo, the email in Chinese. Even if I had done that, I would have no idea what it said.

Page 231

So I'm depending on what I have in my hand.
Q. Do you know what --
A. Which is an English translation.
Q. I'm sorry to interrupt.
A. That's pretty clear. Right?
Q. Do you know what irbesartan is?
A. Yes, it's another -- another sartan.
Q. And have you studied irbesartan, as you have valsartan?
A. Have I studied it? I don't know what you mean by that.
Q. Have you -- have you investigated the potential or not of nitrosamine formation in irbesartan?
MR. SLATER: Stop for a second.
Are you asking if he's done anything --
Well, you know what, you can just go ahead and answer the question. I don't care.
A. Only in this email.
Q. Okay. And is it fair to say, or do you not know, that irbesartan is a different drug molecule from the generic valsartan API?
A. Yes, for sure, it's different.
Q. Just a moment here, my computer is

Page 232

saying it's going to shut down. One second here.
MR. SLATER: The time has come.
MR. BERNARDO: What have you done to my computer, Adam?
MR. SLATER: I released -- I have other people, though. I have people in there.
Q. Sorry. Have you done anything to research the structural differences between irbesartan and valsartan API?
A. I don't have to research it. It's obvious. I mean, if you look at the structure, they're different.
Q. You say in your report at -- and again, I'm sorry, to be clear, your October 2022 report at page 2.
MR. BERNARDO: If you want to pull that up.
Q. That "ZHP acknowledged the possibility of cross-contamination of valsartan API on shared product production lines."
Do you see that?
MR. SLATER: Hey, I'm sorry, what page are you on, in which report? Last year's?
MR. BERNARDO: Correct, Adam, yes.
MR. SLATER: Which page, I'm sorry?

Page 233

MR. BERNARDO: On page 2, I believe.
MR. SLATER: Page 2.
MR. BERNARDO: We'll highlight the language for you.
MR. SLATER: No, it's all right. I just wanted to make sure I was in the right place.
BY MR. BERNARDO:
Q. Do you see that, Dr. Hecht?
A. Yep.
Q. Okay. And you say that "ZHP acknowledged the likely occurrence of cross-contamination." Correct?
A. Yes.
Q. Have you investigated whether in fact any kind of cross-contamination occurred?
MR. BERNARDO: Can you hold -- can we go off the record?
THE VIDEOGRAPHER: Going off the record. The time is 2:04 p.m. Central Time.
(A brief recess takes place.)
THE VIDEOGRAPHER: We are back on the record. The time is 2:12 p.m. Central Time.
BY MR. BERNARDO:
Q. Dr. Hecht, we were talking about cross-contamination. I don't think we got very far,

Page 234

but I think the only point I wanted to establish is, you say that ZHP acknowledged the -- and I think the words you used are "likely occurrence" of cross-contamination. Right?
A. Yes.
Q. Okay. Did you do anything to investigate whether cross-contamination did, in fact, occur?
A. Well, it's in the documents. With the -- they go into a great deal of detail about the cross-contamination of the lines that were used in various processes, which is one way that the dimethylnitrosamine ended up in one of the products that also had diethylnitrosamine.
In other words, from the -- I think there was cross-contamination between the TEA process and the later processes. I'm not exactly sure, but I know, from what I read, there was some cross-contamination in the lines. ZHP mentions that. And that was the source, I believe.
Q. That was my --
A. Of part of the dimethylnitrosamine that they found in the TEA process.
Q. And I think you answered my question, but let me just make sure.

Page 235

The basis for your understanding of what did or didn't occur with respect to cross-contamination is the document you have cited there, the ZHP deviation investigation report. Is that correct?
A. Which document are you talking about now?
Q. The one that's cited that we'll highlight for you in a moment. Right there?
A. Yeah.
Q. Okay. And I just simply want to make sure that that's the totality of what you're relying on with respect to the contamination issue; that you did not do anything to investigate it, additional from that?
MR. SLATER: Additional from reading the documents, is that what you're asking?
MR. BERNARDO: That's exactly what I'm asking.
A. I guess I'm a little confused. Because I mean, before your computer went down, we were talking about something different. We were talking about the irbesartan.
Q. We were, and right before --
A. Then all of a sudden, you're talking about something different. So what's going on here?
Q. I switched -- I finished that topic and moved to this topic.
A. Okay.
Q. And then asked --
A. You didn't ask anything about it.
Q. Well, let me start over. I think we've completed the questions I wanted to ask you, and I think you've answered them. I can go back, but I don't see a need to, unless there's -- you disagree with any of the testimony you've given.
Let me do it this way, so the record is clear.
A. You're asking the questions, so that's fine. It just confused me --
Q. Yeah, I'm sorry --
A. That you jumped from one thing to another, without any notice.
Q. Without a transition. Let me just summarize this, because I think the record is clear, but just to make sure.
You talk about cross-contamination on this page of your report; that's in the first line. Correct?
A. Yes.

Page 236

Page 237

Q. And then you cite to -- and you explained a little bit about what you think happened, with respect to cross-contamination. Right?
A. Yeah.
Q. And I simply wanted to confirm that the basis of your understanding is the document that you cite; that you didn't do anything on your own otherwise to investigate the cross-contamination. And I think you confirmed that, too?
A. Right.
Q. That's all I wanted to do.
I'm going to switch topics, to give you -- we're done with cross-contamination.
Prior to your involvement in this case, Dr. Hecht, had you ever done any research on impurities in pharmaceuticals in particular?
A. No, not pharmaceuticals.
Q. Okay. And in particular, I think this is consistent with what you just said, but just to be sure. So you've never researched the development of nitrosamines in pharmaceuticals, prior to your involvement in this case. Correct?
A. Yes.
Q. Fair to say, therefore, you've never taught on that subject; the subject being the

Page 238

formation of -- let me start with impurities in pharmaceuticals?
A. Not in pharmaceuticals. I mean --
Q. Yeah, I'm purely asking about pharmaceuticals?
A. We did do a study on dishwashing liquids. And of course, we've done a lot on tobacco, but we haven't done pharmaceuticals.
Q. And you've never performed any evaluation of a manufacturer's compliance with CGMP manufacturing practices with respect to pharmaceuticals. Is that fair?
A. Yes, correct.
Q. And you've never conducted testing of any kind for a pharmaceutical company of any of its products. Is that correct?
A. Correct.
Q. And you've never conducted an assessment of a pharmaceutical product. Correct?
A. What do you mean by "assessment"?
Q. Well, I was going to use risk assessment, but you didn't like that phrase earlier?
A. No.
Q. You've never studied a pharmaceutical, previously to this case, to determine what risks the

Page 239

pharmaceutical might present. Is that fair?
A. Correct.
Q. Okay. And you have no experience with respect to pharmaceutical regulation and enforcement. Fair?
A. Correct.
Q. And outside of litigation, you've never reviewed any pharmaceutical regulatory filings. Correct?
A. Correct.
Q. Okay.
MR. BERNARDO: And this is where the word comes up, Adam.
Q. You're not an epidemiologist. Is that fair?
A. I'm not what?
Q. An epidemiologist?
A. That's correct; I'm not an epidemiologist.
Q. And therefore, you don't consider yourself to be an expert in the field of epidemiology. Correct?
A. That's correct.
Q. When was the last time you taught a full-time university course, Dr. Hecht?

Page 240

A. That would probably be about 20 years ago.
Q. And in -- what about a class in organic chemistry, how long ago was that?
A. No, I never taught -- oh, no, that's not true. I taught organic chemistry at Haverford College in 1969.
Q. And when was the last time that you personally utilized gas chromatography?
A. Personally?
Q. Yes.
A. Probably in about 1994.
Q. And what about gas chromatography with flame ionization detector?
A. Yes, the same.
Q. The same answer, okay. 1994?
A. Right.
Q. And what about gas chromatography with mass spectrometry?
A. GC-MS? Personally, you mean I injected the sample?
Q. Correct.
A. No, I worked with -- side by side with somebody else who injected the sample?
Q. Correct?

Page 241

A. I injected the sample?
Q. Yes, that's what I'm asking.
A. Okay. 1995.
Q. And let's ask the question that you're trying to qualify. Explain when was the last time you did what you were describing, where maybe you were standing next to somebody who was doing it?
A. Well, we're still doing it in the lab. So, you know, we use GC-MS and LC-MS every day. We have 15 instruments.
Q. New topic. This is going to be a transition. I want to talk about your invoices. But I can bring them up if you need to refer to them, or we could talk generally.
Let me ask my question, and then you can tell me whether we need to refer to them.
Looking at your most recent invoice that was provided here, it appears that you last billed time, other than one hour that was recently billed, in July of 2021. Is that correct?
MR. SLATER: What he's asking is, what you've invoiced us for.
A. Yeah, I guess that's correct.
Q. How much time since July of 2021 have you devoted to work on this case, just roughly? And

Page 242

July of 2021; I'm asking that, because that's the date of your report?
A. I don't know. Maybe 30 hours or so? I haven't added it all up yet.
Q. Okay. So you've just not billed that time. Is that fair?
A. Yeah, that's right.
Q. Got it. Okay. And Dr. Hecht, I think we talked about this before. You have a lot of experience studying nitrosamines. I understand that; that's fair?
A. Right.
Q. And you've published hundreds of articles about nitrosamines. Correct?
A. Correct.
Q. And given presentations -- and I'm talking generally, nitrosamines?
A. Yes.
Q. And many of them, if I recall, are focused on NNN or NNK, tobacco-specific nitrosamines. Is that correct?
A. Right.
Q. And you've taught university students about nitrosamines generally. Correct?
A. Yes.

Page 243

Q. Okay. Now, is it fair to say that you've never published anything or taught anything with respect to the formation of NDMA in a pharmaceutical product?
A. I don't know about "never." But in general, you know, it's not one of the main topics, for sure. But I mean, there could have been an example in -- I can't think of any offhand. So I'd say yes, it's fair to say.
Q. Okay. And prior to this litigation, fair to say you've never had any discussions with regulators about how DMF can degrade and form nitrosamines in a pharmaceutical product?
A. No, that's not true. Because I was on the FDA panel that looked into this. So there's plenty of discussion.
Q. And when was that?
A. 2021?
Q. I was asking prior to the litigation, Dr. Hecht?
A. Yeah, prior to the litigation. So the FDA panel was established or reenergized around the time when all this was happening, so I forget the exact date. It's either 2020 or 2021. So I mean, I was on that panel. So I participated in a few

Page 244

conference calls, and also at a symposium. So I participated in all that, I don't remember the exact details. But it was either 2020 or 2021.
Q. Okay. You were retained in 2019. Correct?
A. Yes.
Q. So I was asking you whether you've done any of this prior to your retention as an expert in this litigation.
A. Done any of what?
Q. Sorry. The panel you're talking about, you were answering my question --
A. No, that was after.
Q. Okay. So the example you just gave was after you were retained as an expert in litigation?
A. Yes, that's right.
Q. Okay. Thank you. Dr. Hecht, during your last deposition, you were asked about whether or not you disclosed your work for plaintiffs in this case when you participated in that FDA panel.
I don't want to re-hash that; I just want to ask if you recall that questioning?
A. Not really.
Q. Okay. Is it fair to say that you did not disclose your work for plaintiffs, prior to

Page 245

participating in that panel?
MR. SLATER: Objection.
You can answer.
A. You mean disclose to the FDA?
Q. Correct. As a potential conflict of interest.
A. I really don't remember.
Q. Okay. Do you agree that it's important to provide disclosure about whatever kind of work you're doing in connection with papers or publications or panels, so that the people listening to you have an understanding of what role you have? I mean, you have your education; but whether or not you do work for plaintiffs or otherwise? Do you think that's important?
A. Yes --
MR. SLATER: Objection.
You can answer.
Q. I didn't hear your --
A. Yes, it's important.
Q. Okay. And you've previously had issues brought to your attention where you in fact did not disclose your work for plaintiffs in litigation, where you should have. Do you recall that?
MR. SLATER: Objection.

Page 246

A. There might have been -- there might have been one or two.
Q. Okay. And an example of one of them is a paper you wrote with respect to smokeless tobacco, with an author called Dr. Boffetta.
Do you recall that?
MR. SLATER: Objection.
A. I remember the paper for sure.
Q. But you don't remember whether or not you disclosed?
MR. SLATER: Objection.
A. Disclosed what?
Q. The fact that you were a paid expert in smokeless tobacco litigation for plaintiffs?
A. Oh, yeah, right.
MR. SLATER: One second, Doctor.
Objection to this whole line of questioning.
You can answer.
A. I was, yeah. I guess I -- maybe I didn't disclose it, I don't know. I don't know.
Q. And you later --
A. This was like -- this was 20 years ago.
Q. Okay. And you later issued an errata, as a result of being asked to disclose your --

Page 247

A. Yeah.
Q. -- relationship.
A. Right.
Q. Okay.
A. And I probably neglected to disclose it when we wrote the paper. I probably forgot about it.
Q. Okay. You recently published a paper that talks about NDMA forming in valsartan, within the last year, I believe. Correct?
A. Yep.
Q. And it's entitled "Metabolic activation and DNA interactions with carcinogenic n-nitrosamines to which humans are commonly exposed"?
A. Yep.
Q. Okay. And do you agree that in that paper, you also did not disclose that you're a retained expert in litigation involving that very subject?
MR. SLATER: Objection.
You can answer the question.
A. Yeah, actually I did write to the journal afterwards. I did forget to add it in the paper itself, but I did write to the journal afterwards. I can read you the email.
Q. No. I appreciate --

Page 248

A. So I --
MR. SLATER: Let him finish the answer, please.
A. I did write to the journal and disclose that I was a witness in testimony about this subject.
Q. What were the circumstances that caused you to do that, if you recall?
A. Yeah, Slater reminded me.
Q. Okay.
MR. BERNARDO: Reserving time for redirect, and turning it -- oh, I'm sorry, one last question.
Q. Dr. Hecht, we've gone through your two reports; a portion of your 2021 report and the entirety of your 2022 report, and talked about a lot of topics.
I want to just ask you: Are there any points about which you expect to testify pertaining to the subjects we discussed that we haven't talked you about here today?
MR. SLATER: Objection.
You could answer.
A. No. But -- no. Something else could come up, I mean....
Q. But as you sit here today, there's

Page 249

nothing else that you can think of. Is that fair?
MR. SLATER: Objection.
You can answer.
A. Right. I said that.
MR. BERNARDO: I don't have any further questions at this time. I turn it over to my colleagues for other counsel. And as I mentioned a few minutes ago, obviously, I'm reserving the remainder of my time for any redirect, of course, to the extent Mr. Slater does direct.
MR. SLATER: When you say the remainder of your time?
MR. BERNARDO: The remainder of the seven hours that haven't been used, after the other folks ask their questions. I'm trying to make it clear: I may not be done. I have seven hours, and I may ask questions after you're asking them. I think that was pretty clear, but.
All right. Do you want to take a break, Dr. Hecht, before somebody else comes, or should we let -- it looks like maybe Mr. Harkins will ask questions.
THE WITNESS: Yeah, let's keep going.
MR. HARKINS: Can we just take a quick five-minute break or do you want to keep going?

Page 250

THE WITNESS: Let's take a break then.
THE VIDEOGRAPHER: Going off the record. The time is 2:32 p.m. Central Time. This is the end of Media Unit 5.
(A brief recess takes place.)
THE VIDEOGRAPHER: We're back on the record. The time is 2:41 p.m. Central Time. This is the beginning of Media Unit 6.
EXAMINATION BY MR. HARKINS:
Q. Good afternoon, Dr. Hecht.
A. Good afternoon.
Q. My name is Steven Harkins with the law firm of Greenberg Traurig, and I represent the Teva defendants.
You're familiar with the Teva defendants and their role as a finished-dose manufacturer in this case. Right?
A. Yes.
Q. The main thrust of my questioning is going to be find out, in your supplemental report and in the one section of your report submitted in 2021, if you have any criticisms or opinions about the finished-dose manufacturers.
And when I say "finished-dose manufacturers," unless otherwise indicated, I'm

Page 251

referring to both Teva and Torrent, who were the two finished-dose manufacturers involved here. Okay?
A. Okay.
Q. Is that a yes?
A. Yes.
Q. Can you hear me okay?
A. Yes.
Q. All right. Generally speaking, you understand that this upcoming trial involves the ZHP API that was used by both Teva and Torrent in their finished-dose valsartan drug product. Right?
A. Yes.
Q. And looking at your supplemental report that was submitted back in October of 2022. Do you have a copy of that, or would it be helpful for me to share that?
A. Yes.
Q. In this report, are you intending to offer any opinions with regard to the finished-dose manufacturers?
MR. SLATER: Objection.
You can answer.
A. No. I mean, they received the material from ZHP. ZHP created the faulty material. And I guess it's -- you know, it's their responsibility

Page 252

to -- well, I don't know. I mean, someone along the line has to figure out that, you know, this process that was being used was not correct. And, you know, that it presents the potential problem of nitrosamine contamination.
Q. And we'll go through this; I'll give you more opportunities to talk about specific sections of that report. But I just want to generally, you know, see if you agree that the main thrust of your report, your supplemental report, are criticisms of ZHP, and there are some areas that might apply to the finished-dose manufacturers?
I just want to understand if that's fair?
A. Right, that's correct.
Q. Then looking at the report that you submitted on July 6, 2021, I believe that's already been marked as Exhibit 1. Do you have that report with you as well?
A. Yeah.
Q. There is a section that starts on page 25 of your report, under the Heading 6, and it's titled "Nitrosamines in the Teva Finished Dose Formulation"?
A. Yes.

Page 253

Q. And I just want to make sure that we understand if there's anything in this report that we need to address, I want you to take a moment and look at the first paragraph of this section, and read through it quickly. And -- or I'm sorry; read through it at your own pace, and let me know when you're finished.
(Brief pause in proceedings.)
A. Yeah.
Q. Am I correct that this paragraph describes the product that is manufactured by API received from ZHP and Mylan by Teva. Correct?
A. Right.
Q. It's a factual paragraph?
A. Yes.
Q. It wasn't intended to be an opinion or criticism of Teva's conduct. Right?
A. Correct.
Q. The next paragraph, I believe, indicates levels of NDMA identified by Teva in their valsartan product, testing on the ZHP product. Go ahead and take a look at it, and just -- my question is: Is this just another factual paragraph describing that topic?
A. Yes.

Page 254

Q. This paragraph doesn't contain any opinions or criticisms of Teva's conduct. Right?
A. Right.
Q. And the final paragraph, again, just to -- I'm sorry, the third paragraph, again, just to go through, is discussing the NDEA testing levels in the Mylan product, and is similarly just a factual paragraph. Right?
A. Right.
Q. It doesn't contain any opinions or criticisms with respect to Teva?
A. Right.
Q. Then the final paragraph says, "These contamination levels caused an unreasonably dangerous and unacceptable risk of causing or substantially contributing to the causation of cancer for those ingesting the valsartan sold by Teva."
A, did I read that correctly?
A. Yes.
Q. And B, that was part of your general causation opinion that you previously provided. Correct?
A. Right.
Q. So Dr. Hecht, turning back to the report that you submitted in October of this case, and

Page 255

looking at the first paragraph?
A. Yeah.
Q. And I believe you said this generally, but I just want to be clear.
In the first paragraph here, you state that the purpose of this report is to provide further discussion of your conclusions as what ZHP -- I'm sorry; to supplement your opinions with respect to ZHP. Is that correct?
A. Yes.
Q. And the second paragraph indicates a summary of your supplemental opinions and conclusions as what ZHP could or should have done?
A. Yes.
Q. You don't mention either of the finished-dose manufacturers, including Teva, anywhere in those two paragraphs. Right?
A. Right.
Q. And turning down through your report -- and I'm happy to let you take more time to look. But I will say, the only place in your report, the supplemental report submitted in October, that I see a reference to Teva and Torrent in the body of the report is at the bottom of page 10; if you can turn to that.

Page 256

A. Yep.
Q. And the statement that you're making with regard to Teva and Torrent here is just to report the levels of impurities that were found in their finished dose product. Correct?
A. Right.
Q. And similar to the question I was asking with the other report, this paragraph is not intended to contain any opinions or criticisms of the finished-dose manufacturers; it's factual?
A. It's just facts.
Q. Right. Dr. Hecht, to make sure that we cover anything that may fall into that gray area where you were talking about obligations the finished-dose manufacturers might have, can you turn back to your first report, the July 6 -- 2021, apologies, report, and go to page 18?
A. Okay.
Q. And this is a statement that you discussed already, and I just want to clarify a few things about it from the finished-dose manufacturers' perspective.
At the end of that paragraph, you indicate "a qualified organic chemist in industry would be aware of this literature."

Page 257

A. Where is this now?
Q. Sorry. The bottom of the first full paragraph, on page 18?
A. Oh, okay. Oh. Yes.
Q. And I'm not going to go back over it, but this is the statement that you were discussing with Mr. Bernardo, about the literature that you may have reviewed in connection with coming to this -- to forming this opinion. Right?
A. Yes.
Q. Does this opinion in your report apply equally to the organic chemists working for the finished-dose manufacturers, like Teva and Torrent?
MR. SLATER: Objection.
You can answer.
A. Yeah, I would think that anybody doing organic chemistry should have at least a passing knowledge of what the hazards of various compounds are, yeah. And of their place in the overall firmament of organic compounds. And, you know, nitrosamines have a special place.
Q. And I think I understand your testimony on this from earlier today, so I'm not going to go back over that. I just want to clarify a few things that I don't know if they were exactly clear on the

Page 258

record, in a slightly narrower fashion.
You discussed the world of literature, and sort of the body of scientific knowledge surrounding these issues. I just want to confirm: You are not aware of any literature, prior to June 2018, that discussed the potential for nitrosamine impurities, specifically in valsartan API or valsartan drug products. Correct?
MR. SLATER: Objection.
You can answer.
A. Published literature, or any --
Q. Published literature?
A. Published literature. That specifically related to valsartan?
Q. Yes.
A. Is that the question?
Q. Yes.
A. No, I don't think there was any, unless I'm forgetting something.
Q. And in your review of material in this case, you haven't seen any document that indicates that Teva specifically was aware of the potential for nitrosamine formation in valsartan API or valsartan drug product, prior to June 2018. Correct?
A. Prior to when?

Page 259

Q. June of 2018?
A. Correct.
Q. And Dr. Hecht, one more thing as we're just kind of cleaning up stuff on your report, I just want to make sure that I'm clear.
Looking at the supplemental report that you submitted, the October 31st, 2022, report, and specifically going to the list of supplemental materials reviewed that begins on Exhibit A. Let me know when you're there.
A. Yeah.
Q. So the first page of this is all under a heading that includes ZHP documents. Correct?
A. Yes.
Q. And then on the second page, there are a handful of Torrent documents as well. Correct?
A. Yes.
Q. And then there are four deposition transcripts here.
A. Yeah?
Q. And I believe all four of those deposition transcripts are ZHP witnesses. Is that correct?
A. I think so, yeah.
Q. There are no additional Teva documents

Page 260

included on the list of supplemental materials reviewed. Correct?
A. Right.
Q. And Dr. Hecht, turning now back to your July report, there is an exhibit that has a similar list of the materials that you reviewed. I believe it's Exhibit -- I believe it's Exhibit 2 to your July 7, 2021 report. If you could go ahead and take a look at that.
A. Which exhibit is it?
Q. It's Exhibit 2?
A. All right.
Q. And I believe it's unnumbered.
A. Okay. "Documents Reviewed."
Q. And there's a header --
A. What's your question?
Q. Sure. I just want to confirm: There's a header for ZHP documents again, and that goes on until the third page --
A. Right.
Q. -- of this exhibit. Then there are Hetero and Mylan documents?
A. Right.
Q. And then there's a list of 13 Teva documents. Do you see that?

Page 261

A. Right.
Q. And just so I'm clear: In forming your opinions, both in your initial report and in your supplemental report, these are the only 13 Teva documents that you reviewed?
A. Correct.
Q. All right. Dr. Hecht, if you could turn back to the body of your July 6, 2021, report. Oh, I apologize. The supplemental report.
MR. SLATER: What did you say? I lost it, I missed it?
MR. HARKINS: I identified the wrong report. The next question is about the supplemental October report.
A. Okay.
Q. Strike that again. I'm getting my reports mixed up.
I apologize, Dr. Hecht. This question is about the July report, and specifically on page 23 of that report.
A. Okay.
Q. So at the top of that, there's a paragraph that starts in the middle, and beginning in the second line, you have a sentence after a comma, I'm happy to read the beginning of it. It says,

Page 262

"Thereafter, when aberrant peaks demonstrated unaccounted-for impurities, the nitrosamine contamination could have been easily discovered, based on knowledge of the potential chemical reactions and application of GC-MS to identify potential NDMA/NDEA."

Did I read that correctly?

A. Yes.

Q. And then it says, "This was identified by Novartis, even without the full information available to ZHP."

Did I read that correctly as well?

A. Yes.

Q. At the end of that statement, you say, "the full information available to ZHP."

What do you mean by that?

A. Well, it took -- according to my understanding, ZHP never thought of the possibility that dimethylnitrosamine could form in this process. Of if they had thought of it, they never mentioned it. But Novartis, the guy at Novartis, figured it out by, you know, taking into consideration the process.

So, you know, he's the one, according to my understanding, he's the one that figured out

Page 263

dimethylamine could have been formed from DMF, and, you know, once he saw that, then obviously the light bulb went off.

Q. Doctor, are you familiar with the FDA's review process for approving DMFs and ANDA applications?

A. Not very.

Q. So would you say you have an understanding of what information in the Drug Master File is or is not available to a finished-dose manufacturer when they submit an ANDA?

A. It's not my area.

Q. And you haven't reviewed Teva's ANDAs that were submitted in this case?

A. Pardon?

Q. Sorry. You have not reviewed the ANDA files submitted by the finished-dose manufacturers, Teva and Torrent, in this case, have you?

A. No.

Q. Do you have any understanding -- I believe you may have already answered this, but just to be clear -- do you have any opinion or understanding as to what a finished-dose manufacturer like Teva does or does not have access to, in the ZHP DMF when they submit those ANDAs?

Page 264

A. Well, I can imagine what it -- what it would be, but I don't have a -- I mean, when you say do I have an understanding; sure, I have an understanding if it -- you know, if somebody would show it to me and discuss it with me. I mean, it's not something that's forefront in my mind.

Q. You don't have an opinion generally about what types of information a finished-dose manufacturer has access to, in submitting an ANDA that refers to a DMF. Right?

A. You're saying I don't have an opinion?

Q. I guess before I get to this specific question, I was hoping to ask a more general one.

The specific question is going to be: Have you reviewed documents to determine what information on the ZHP process was available to the finished-dose manufacturers, when they submitted their ANDAs for the valsartan product prior to 2018?

A. No, I haven't.

Q. And then the more general question is: Do you generally have an opinion or knowledge of what types of information is available to a finished-dose manufacturer, in that type of situation?

A. No.

Q. So I understand, and correct me if I'm

Page 265

mischaracterizing, that it's your opinion ZHP should have recognized the potential for nitrosamine formation in the API, based on the information that was available to ZHP. Correct?

A. Yes.

Q. But you have not undertaken to analyze whether the finished-dose manufacturers, including Teva, should have recognized the potential for nitrosamine formation, based on the information that was available to them about ZHP's process at the time they submitted their ANDAs?

A. No, I haven't looked at that.

Q. I believe you testified earlier that -- though I understand you think differently about what ZHP should have done -- you testified that if ZHP had no reason to think nitrosamines could form, there would be no reason for ZHP to test for nitrosamines. Is that accurate?

MR. SLATER: Objection.

You can answer.

A. Could you repeat that?

Q. Sure. I believe you testified earlier today that, assuming ZHP had no reason to think nitrosamines could form, there would not be a reason for them to test for nitrosamines in their valsartan

Page 266

drug product?
MR. SLATER: Objection.
You can answer.
A. That question doesn't make sense to me. I mean, I don't see how they could assume that.
Q. Sure?
A. Considering in the process they used. I mean, that's the whole basis of my testimony. I don't see how they could possibly assume that.
Q. And I understand that, Dr. Hecht. And I believe the exact way the question was phrased to you is: Understanding that you think they should have had a reason to think nitrosamines could form, asking for purposes of the question that to -- I'm sorry.
You were asked, for purposes of the question, to assume that they had no reason to think that they would form. I'm just confirming that your testimony from today was: If, assuming ZHP had no reason to think nitrosamines could form, there would be no reason for them to test for nitrosamines?
MR. SLATER: Objection.
You can answer.
A. I guess so, but I'm really not sure. Because -- you know, I have trouble with the first -- your assumption, your presumed assumption, I have

Page 267

real trouble with that. I have trouble getting my mind around the fact that they could possibly have not thought of this, even though they didn't.
So you're asking me to assume that they didn't think of it. So I guess, yeah, if they didn't think of it, you know, then -- you know, the second part would make sense. But I can't see how they couldn't think of that. Does that make sense?
Q. Yes, Doctor. And I understand your concern, and that you disagree with the premise that I'm asking you to assume for the question. I totally understand that.
My next question is: Would that same logic hold true for the finished-dose manufacturers? If the finished-dose manufacturers had no reason to think that nitrosamines could form in the valsartan drug substance, there would be no reason for the finished-dose manufacturers to test for nitrosamines?
MR. SLATER: Objection.
You can answer.
A. That's probably true. I mean, I think I have more sympathy with the finished-dose manufacturers than I do with the ZHP. But of course, the finished-dose manufacturers, I'm sure, are well aware of the procedures that are used to prepare the

Page 268

API. So really, that's a little surprising to me that only Novartis could think of this. I don't really know what's wrong with the other ones.
Q. Apologies; I just want to make sure you're finished?
A. I'm finished.
Q. I just want to clarify the last response, just so I'm sure.
You just stated that you assume they have some information about the API process, but I believe you just testified that you have not reviewed documents to form an opinion about what information from ZHP's DMF on the process was available to the finished-dose manufacturers. Correct?
A. Yeah, that's true, I -- I don't know what was available. Yeah, it's just an assumption on my part.
Q. Dr. Hecht, turning to just another one of these statements I want to make sure we don't miss. On your initial July report, on page 11 --
MR. SLATER: The 2022 report, you said?
MR. HARKINS: Yes.
MR. SLATER: Okay.
A. Yep.
Q. So I've got -- I must have mixed these

Page 269

two up. I apologize. The supplemental report on page 11?
MR. SLATER: The October 2022 report, right?
MR HARKINS: Yes.
A. Okay.
Q. This is into your Conclusions section here, Dr. Hecht, and I just want to understand the conclusion sentence here that starts with, "The available knowledge and technology should have been applied to add straightforward testing for NDMA and NDEA of each batch of API and finished dose manufactured using the API with these processes, which would have revealed the process of NDMA and NDEA."
Did I read that correctly?
A. Yes.
MR. SLATER: Objection. I think you might have missed a couple of words.
Q. Dr. Hecht, this statement includes the finished-dose manufacturer. Is this intended to be an opinion about testing that the finished-dose manufacturers should have also added to their manufacture of valsartan finished product?
A. Yes.

Page 270

Q. And my question, generally speaking, is: What guidances or standards do you feel should have caused the finished-dose manufacturers to add this type of testing to their product, to the extent that you reviewed it and considered it in forming that opinion?

A. Well, the finished-dose manufacturer, I assume, is familiar with the process that was used to prepare the API. That's my assumption; that they certainly ought to be aware of that. And of course, they also do testing of the API before they put it into the finished dose.

So again, I come back to Novartis. I mean, Novartis thought of this. So I don't see why somebody at Teva or one of these other companies that use the API couldn't think of it.

Q. So -- and Doctor, I just want to make sure I understand the two areas you talked about there. One was their analysis of the process for the manufacturing of the API; and I believe the other one you said was their own testing, the finished-dose manufacturers' testing of the API that they're using. Are those the two areas? Did I get that right?

MR. SLATER: Objection.

You can answer.

Page 271

A. Well, yeah. Both.

Q. So turning to the first one that you discussed, the analysis by the finished-dose manufacturers of the API process. I believe we've already set out and established that you did not undertake to review what, if anything, about that process was known to the finished-dose manufacturers. Correct?

A. Could you repeat that?

Q. It's the same question we were going over. You did not review what information was available to the finished-dose manufacturers when they were evaluating ZHP's process. Correct?

A. Right. No, I didn't review that.

Q. And you don't have opinions on what is generally available, as part of that review process, to a finished-dose manufacturer. Correct?

A. I don't know much about it. But, you know, it's my assumption that the basic methodology to prepare the API would be made clear to the finished-dose manufacturer. That's my assumption.

Q. Turning to the second area that you talked about, their testing of the API, I'd like to refer you to page 20 of your initial report, the July report.

Page 272

MR. SLATER: Tell me what page again, Steve?

MR HARKINS: 20.

MR. SLATER: 20, thank you.

A. Okay.

Q. If I have this backwards again, I'm going to be...

At the bottom of this page, I believe it is the third-to-last sentence, it says, "In their analyses of the product, they would not have identified NDMA in the chromatograms unless they were specifically looking for it, because the peaks were too small."

Did I read that correctly?

A. Right.

Q. That's an opinion about ZHP. Correct?

A. Yes.

Q. And from your testimony earlier today, you agree that, in order to find NDMA in valsartan testing, you need to be looking for it.

A. Right.

Q. And you testified that ZHP would not have identified NDMA through routine chromatography testing of the API?

A. Most likely.

Page 273

Q. And I apologize; I want to make sure. Were there peaks, or would there be peaks, in routine chromatography testing of the API that would be large enough for ZHP to have identified it?

A. There were small peaks. But they didn't further investigate the small peaks.

Q. Were the peaks large enough that they would have been noticeable, and allowed detection of NDMA on routine chromatography testing?

A. Probably not. Again, you know, with a peak that size, you have to develop a method to look for it specifically. You know, like a routine GC-MS analysis or LC-MS analysis, you know, it would just appear as a small peak.

So, you know, unless you were -- unless you had some knowledge, like the guy at Novartis, to look for it specifically, then you wouldn't -- you probably -- you might not even notice it. So no, you would focus on the larger peaks, which were all like solvent residues and stuff.

Q. My question is just that the same holds true for the finished-dose manufacturers: They would not have identified NDMA in the chromatograms of API unless they were specifically looking for it, because the peaks would be too small?

Page 274

A. Probably. But Novartis did. So.
Q. And as far as testing -- apologies, were you finished?
A. Yep.
Q. And as far as testing of the finished-dose product itself; again, the finished-dose manufacturers looking at chromatograms on the finished-dose product would not have identified NDMA unless they were specifically looking for it. Correct?
A. Probably.
Q. And I just want to make sure I'm getting the terminology right.
When you say, "identified NDMA in the chromatograms," are you talking about analysis of the raw data and imaging that results from chromatography?
A. I don't know about imaging. But I mean, you get a chromatogram, which is a series of peaks. Okay? And the NDMA peak, when it's detected by flame ionization detection in this circumstance, would be quite small. So since there were larger peaks in the same chromatogram, you know, you might ignore the small NDMA peak.
Does that answer your question?

Page 275

Q. I think so, and I think I probably just said it inartfully.
When you talk about what would be shown in the chromatograms, we're talking about the data, and then the graphical representation of the peaks?
A. Yes. The graphic -- the chromatogram is a graphical representation of the peaks. You know, there's a baseline, and it goes up, and it comes down again, and it goes up again and comes down again. It's like a mountain range. Not exactly, but, you know, the peaks are -- that's why they're called "peaks."
Q. And the review of that chromatography data in the graph by the finished-dose manufacturers would not have identified NDMA unless they were looking for it, because the peaks were too small?
A. Well, I can't exclude the fact that it could have been identified. All right? I'm just saying that in the absence of other information, when they looked at the chromatogram, the NDMA peak is going to be quite small compared to the other peaks. So they would not have first noticed it. All right?
They would -- they'd look at the big peaks first; I mean, anybody would do that. So there would be a small peak that was actually the NDMA, but

Page 276

they might ignore it completely.
Q. And I think I understand your opinion with regard to other ways that it could have been identified; I just want to be clear. Analysis of chromatography from the routine testing by the finished-dose manufacturers, just that piece, would not have identified NDMA, because the peak is too small?
A. Well, no, that's not true. I mean, if they used GC -- if they had used GC-MS, for example, or LC-MS, rather than GC-FID, you know; or LC with UV detection; in other words, if they used a more specific method, like Novartis did, then they would have seen it clearly.
Q. And Dr. Hecht, I just want to be clear. I'm not talking about other investigational methods, or other ways that they could have identified it. I'm just -- I'm just trying to clarify, because I think I used the wrong term.
It's your opinion that use of the routine detection method from chromatography by the finished-dose manufacturers on the valsartan API in this case would not have identified NDMA, because the peaks generated by that testing would be too small?
MR. SLATER: Objection.

Page 277

You can answer.
A. Well, that depends on how you define "routine." So --
Q. Doctor --
A. If they used GC mass spec, and they monitored multiple different ion transitions in the same run, which is definitely possible, then they might have seen a larger peak for NDMA. But you know, if they used GC-FID, then the peak is going to be quite small, compared to like solvent residue peaks. So you know, it depends on how they did this, how they did the work.
Q. And Dr. Hecht --
(Court Reporter Clarification.)
Q. And Doctor, I apologize if I've confused the question.
You're aware that GC-FID was the detection method -- you're aware of the detection method that was approved in the ANDA specifications for performing chromatography on valsartan API in the relevant ANDAs, or are you not?
A. No, I don't know what the approved method was. Was it GC-FID, or, I don't know. Or was it GC-MS?
Q. I'll represent to you that it was not

Page 278

GC-MS.

Using the methods that you discussed previously with reference to the ZHP API that we were talking about, where you indicated that using that method of routine chromatography testing, ZHP would not have detected NDMA in their API on routine chromatography testing; I'm asking you to assume the same method of routine chromatography testing for the finished-dose manufacturers. Do you understand?

A. Yeah, right.

Q. Using that method of chromatography testing to analyze raw chromatography data on the incoming API, the finished-dose manufacturers would not have identified the NDMA because the peaks would have been too small?

A. Well, I mean, I have to say that really depends on the operator. Okay? I mean, I've had years of experience with this. And, you know, I'm in the office, the guy who's running things in the lab. So there are differences, you know.

Some people in the lab will look at every small peak, and question it. Others will say, oh, that's just a small peak; we don't have to worry about it. So it really depends to some extent on the operator, and also on the question that's being

Page 279

asked.

Q. Doctor, are you familiar with the release standards for valsartan API, as far as identification of unknown impurities that show up on chromatograms?

A. No.

Q. That's not something you reviewed in connection with your work in this case?

A. Not specifically, no.

Q. Are you familiar with the specifications put in place in the ANDAs for approving use of APIs, based on levels of unknown impurities that are identified in that API?

A. It's not really my area. I'm not that familiar with it.

Q. Are you familiar with the ICH guidances that set certain target standards for the pharmaceutical industry as a whole to use in evaluating unknown impurities in their API?

A. No.

Q. Are you familiar with a plaintiff's expert who testified last week named Philip Russ?

A. No.

Q. Have you reviewed anything that Mr. Russ has submitted in connection with this case?

Page 280

A. No.

Q. Do you have any understanding of what Mr. Russ's opinions are?

A. I don't know Mr. Russ. I don't think I've read anything by Mr. Russ.

Q. I'm going to ask you to assume for the purposes of the next question that Mr. Russ has testified that the specifications in place for release of valsartan API would not have been exceeded by any of the ZHP API used in manufacturing by any of the finished-dose manufacturers.

Can you assume that, just for purposes of this question?

MR. SLATER: Objection.

You can answer.

A. Could you repeat that?

Q. You've testified that you don't know the standards that are applicable to determining whether to release and use the API under either the ANDAs, ICH, or any of those other guidances. Right?

A. Yeah, right.

Q. I'm going to ask you to assume, for purposes of this question, that plaintiff's expert, Philip Russ, has testified that none of the ZHP API used by any of the finished-dose manufacturers would

Page 281

have exceeded the minimum specifications for unknown impurities, like NDMA, in any of the products used to manufacture their finished dose.

I'm going to ask you to assume that, for purposes of my next question. Okay?

A. All right.

MR. SLATER: And I'm objecting to it, because there's serious issues with that question. I'm not going to speak about it, but I have serious issues with that question.

Q. So Dr. Hecht, assuming that the routine chromatogram did not exceed any of the specifications in place, that operator would have no reason to think that nitrosamines specifically were forming, based on their review of the chromatograms in testing that API?

MR. SLATER: Objection.

You can answer.

A. Right. If the operator didn't know anything else, you know, there would be no reason for them to suspect that the small peak was NDMA. You know, if they're -- if they didn't know anything about the process used to manufacture the API.

Q. All right. Dr. Hecht, I believe you testified that your opinions about how prevalent

Page 282

GC-MS is in the pharmaceutical industry are based, at least in part, on discussions with former students and colleagues who have gone and worked in the pharmaceutical industry. Is that right?

MR. SLATER: Objection.

You can answer.

A. I mentioned that, but really, a much better example is the ASMS meetings. There you will see literally hundred of papers from the pharmaceutical industry using mass spectrometry, LC-MS and GC-MS. That's really a much better example than, you know, what my former students might have said. That wasn't really a very good example, although it has happened.

But the ASMS is really the right answer to that.

Q. And Doctor --

A. ASMS is the American Society For Mass Spectrometry. They have an annual meeting.

Q. And Dr. Hecht, my next question, just -- I know this is not the main thing you're saying you're relying on. Are any of those students currently, or have they worked, for any of the defendants in this case, if you know?

A. Not for -- oh, no. I don't think so,

Page 283

no.

Q. And just because we have a couple of different entities; the Teva entities include Teva, Actavis, Watson and Aero are all sort of involved?

A. No, no.

Q. Doctor -- I'm sorry, Dr. Hecht, apologies. Are you familiar with USP monographs?

A. USP monographs?

Q. Yes.

A. No.

Q. Do you understand what is set out in the USP monographs, as far as testing that's performed on drugs and drug substances?

A. No, I'm not familiar with it.

Q. Are you aware of the types of tests that are specified to perform specific assays in connection with USP monographs?

A. No.

Q. Are you aware of how many USP monographs there are?

A. No.

Q. I'll represent to you that in the plaintiff's expert report, Laura Plunkett's report, she identifies over 5,000 such monographs that are currently approved by USP. I would ask you to assume

Page 284

that for purposes of this question, okay?

A. Okay.

Q. Are you aware of how many of those over 5,000 monographs require testing with GC-MS to perform a specified assay?

A. I have no idea.

Q. And Dr. Hecht, again, for purposes of this question, I'll represent to you that of those over 5,000 monographs, only four require the use of GC-MS to perform a specified assay.

A. Yeah.

Q. Assuming that's accurate, just for purposes of this question, would that change your opinion in any way on how regularly GC-MS is used in the pharmaceutical industry?

A. No.

Q. Okay. And I believe I -- I believe I heard you correctly today that there's nothing we could show you on that that would change any of your opinions today. Correct?

A. Well, I wouldn't say nothing, but --

MR. SLATER: Objection to the form.

A. You know, well, okay. I don't know about the whole pharmaceutical industry, but. So you're the expert.

Page 285

Q. No, I promise you I'm not, Dr. Hecht. I just want --

A. Well, I mean, I don't know, you know, what percentage of all drug companies actually have mass spectrometry. I really don't know. It's my assumption that it's very widely used in the pharmaceutical industry. I'd be shocked if that's not the case. But that's just an opinion. I don't -- I don't really have facts to back that up.

MR. HARKINS: All right. Dr. Hecht, those are all the questions that I have for you. I believe one of the other defendants may have some questions.

It might help to take a quick break just to clear that up?

THE WITNESS: Okay.

THE VIDEOGRAPHER: All right. Going off the record. The time is 3:35 p.m. Central Time. This is the end of Media Unit 6.

(A brief recess takes place.)

THE VIDEOGRAPHER: We're back on the record. The time is 3:49 p.m. Central Time. This is the beginning of Media Unit 7.

MR. BERNARDO: Dr. Hecht, during the break, Mr. Slater and I were doing a little bit of

Page 286

housekeeping, and I just want to the record to reflect the accurate numbers, so we can have the proper exhibit marked.

Earlier, when I asked you how many binders you had with you, your answer was eight. And we got copies of them from Mr. Slater, and there were only seven. And I understand during the break you went back and recounted, and there were, in fact, seven binders you have with you, not eight. Is that correct?

THE WITNESS: Yeah, it only seems like eight. Yes, seven is correct.

MR. BERNARDO: Okay, thank you.

Brittney?

MS. NAGLE: All right.

EXAMINATION BY MS. NAGLE:

Q. Hi, Dr. Hecht. My name is Brittney Nagle, and I represent the Torrent defendants. I'm going to be asking you a brief set of questions just to wrap up on behalf of Torrent today.

Dr. Hecht, first I want to look at your July report, July 2021.

A. Yeah.

Q. And I'd like to draw your attention to Section 7, which begins on page 26 of the report.

Page 287

MR. SLATER: You said 27?

MS. NAGLE: It's Section 7, page 26.

MR. SLATER: Oh, got it.

Q. Dr. Hecht, do you see the Section 7 is entitled, "Nitrosamines In the Torrent Finished-Dose Formulation." Correct?

A. Yeah.

Q. And Dr. Hecht, a few minutes ago, do you recall Mr. Harkins asked you some questions about the section that precedes this section about Teva?

A. Yes.

Q. Do you remember that?

A. Yes.

Q. So Dr. Hecht, I just want to confirm, in line with how you testified earlier, that the information contained in this section is intended to be like factual information. Is that correct?

A. Yes.

Q. And this section isn't offering commentary on Torrent's conduct. Correct?

MR. SLATER: Objection.

You can answer.

A. I have to read over it. Just hold on a second.

Q. Of course.

Page 288

A. Well, the first three paragraphs are statements of fact. I believe that the fourth paragraph is also a statement of fact.

Q. Okay. So this section just contains factual information with respect to Torrent's finished drug product?

A. Correct.

Q. Okay.

(Court Reporter Clarification.)

MS. NAGLE: Finished drug product.

Q. And while we're looking at the July report, Dr. Hecht, can we turn your attention to Exhibit 2 of your report, which is your "Materials Relied Upon" list?

A. What page?

Q. I am looking at a version that has been broken out separately, and it is at the bottom of page 4 out of 6.

A. I'm confused now, now what are you --

Q. Exhibit 2?

A. Exhibit 2.

Q. Exhibit 2 to your July report?

A. Yes.

Q. It's "Documents Reviewed," and if you scroll down --

Page 289

A. Oh, right.

Q. Look at the fourth page?

A. Yeah, okay.

Q. Okay. And you see the section labeled "Torrent Documents"?

A. I'm not there yet.

Q. Okay.

A. Okay.

Q. Okay. So Dr. Hecht, this lists seven documents. Correct?

A. Exhibit 2 of -- Exhibit 2, yes -- seven documents.

Q. All right. And Dr. Hecht, do you recall if you reviewed any additional Torrent documents that are not included on this list, in connection with your July report?

A. No. No additional.

Q. Okay. All right. So Dr. Hecht, let's take -- or let's turn to your October 2022 report, please.

A. Okay.

Q. And similarly, I want to look at the Exhibit A to your report, which is the "Supplemental List of Materials Reviewed." Can you let me know when you're there?

Page 290

A. Yes.
Q. Okay. So on this list, we see that there's a section labeled "Torrent Documents," and it includes four documents?
A. Yes.
Q. Are there any other documents that you reviewed with respect to Torrent that are not listed here?
A. No.
Q. And Dr. Hecht, in your review of materials in this case, you haven't identified any document that indicates that Torrent was aware of a potential nitrosamine formulation in the valsartan API or valsartan drug product, prior to June 2018. Correct?
A. Correct.
MS. NAGLE: Dr. Hecht, that is all the questions I have for you today. Thanks very much.
THE WITNESS: Okay.
MR. SLATER: All right. So let's take a -- let's go off and take about ten, 15 minutes. I hope -- if we come back quicker, we'll be back quicker. But when we come back, I'll have a few questions. And I understand all defense counsel has finished their questioning for now, subject to what I

Page 291

ask. So hopefully, we won't be too long and we can get it done.
THE VIDEOGRAPHER: All right. Going off the record. The time is 3:55 p.m. Central Time.
(A brief recess takes place.)
THE VIDEOGRAPHER: We're back on the record. The time is 4:12 p.m. Central Time.
EXAMINATION BY MR. SLATER:
Q. Doctor, I just have a few questions on a couple of things you were asked about, and one or two things I'd like to confirm. Okay?
A. Okay.
Q. First of all, all the opinions you've offered today in your testimony; have they all been offered to a reasonable degree of scientific certainty?
A. Yes.
Q. And does the same hold true for all the opinions set forth in your reports?
A. Yes.
MR. SLATER: And Chris, why don't we mark as the next exhibit, which I think is 25, Dr. Hecht's CV.
MR. BERNARDO: I think we're up to 26, Adam.

Page 292

MR. SLATER: We're up to 26?
MR. BERNARDO: I believe so.
(A discussion is held off the record.)
MR. SLATER: Whoever is the technical person running this, can you allow Chris to share his screen to put a document up, or upload it or whatever?
MR. GEDDIS: It's uploading. I can screen share.
MR. BILY: You should be able to screen share.
MR. GEDDIS: Do want me to put it on the screen?
MR. SLATER: Yeah, I mean, put it up. But we've got to get it to everybody.
You're saying you're not able to share it in your share file?
He's having trouble getting into the share folder. He doesn't have permission to upload.
MR. BILY: I'll put my email in the chat. Just quickly send it to me, and I can upload it.
MR. SLATER: All right. If there comes a point, Counsel, when you say, "Hey, we need that document," Chris will just pause to send you

Page 293

whatever.
Most of what I'm asking about is things you have, and I'm only going to use a couple documents. But obviously, stop us if you need something; we'll get it to you.
MR. BERNARDO: Will do, thank you.
MR. SLATER: All right. So first of all, that's the CV. I assume I don't need to get that to you guys before we ask some questions about it?
MR. BERNARDO: Correct.
MR. SLATER: Okay. But for the record, the CV will be Exhibit 26.
(Exhibit Hecht-26, Curriculum Vitae of Stephen S. Hecht, Ph.D., Nine Pages, was received and marked for identification.)
Q. Doctor, on the screen what we have is Exhibit 26, and that's the CV you just provided us, I think a few days ago.
Is that your up-to-date curriculum vitae?
A. Yes.
Q. And does it describe your education, professional experience, publications, and other professional accomplishments?

Page 294

A. Yes.
Q. Okay. All right.
MR. SLATER: Let's take that down.
Q. Now, the next thing I would like to do is ask you just a couple of questions. You were asked some questions about what ZHP or others would be expected to know, and I just want to ask you one or two things along those lines. Okay?
A. Okay.
Q. With regard to those chemists who were involved in developing and assessing and managing the TEA with sodium nitrite quenching and zinc chloride manufacturing processes, if they had performed -- and I'm quoting now -- "a sound scientific appraisal of the chemical reactions involved in the synthesis, impurities associated with raw materials that could contribute to the impurity profile of the new drug substance, and possible degradation products," would that, in your opinion, have encompassed the information you've told us throughout your deposition that should have been known to the people who developed and assessed this process, these processes?
A. Yes.
Q. And is that for the reasons you told us earlier, about the availability of this information

Page 295

in the scientific literature?
A. Yes.
MR. BERNARDO: Object to the form of the question.
Q. Similar question, if the people who were -- the chemists who were involved in these processes had applied science-based decision-making with respect to the potential risks of those processes, would have, in your opinion, encompassed the information you've told us throughout the deposition that they -- that ZHP's chemists, you told us during the deposition, should have understood? And I think you used the word "awareness"?
A. Yes.
Q. Okay. In your opinion, did the chemists that were involved in the development and assessment and oversight of this process -- these processes, both of them; in your opinion, did they apply sound scientific evaluation and appraisal of these processes in evaluating the risks?
MR. BERNARDO: Object to the form of the question. Vague, compound.
A. No.
Q. And is that for the reasons you've told us throughout the deposition, in terms of their

Page 296

failure to evaluate the potential presence of amines, that would then be impacted by the sodium nitrite to create nitrosamines?
A. Yes.
MR. BERNARDO: Object to form.
A. When they decided to use nitrite in the reaction mixture, they should have thought about nitrosamine formation.
Q. I'm now going to ask you about a document I know you've seen, which is the FDA warning letter, November 29, 2018. And I'm going to go to the fourth page of that.
In the context of the questioning that defense counsel asked you, about what the FDA's views on this situation are and were. Do you remember, you were asked some questions about that earlier?
A. Yes.
Q. I'm going to read now from the FDA warning letter.
MR. BERNARDO: Adam, which one?
MR. SLATER: Sorry. This is the FDA warning letter dated November 29, 2018, which is whatever exhibit we're up to now, which is I guess 27, which was marked as ZHP Exhibit 213 during discovery.

Page 297

(Exhibit Hecht-27, FDA Warning Letter 320-19-04 dated November 29, 2018, previously marked ZHP-213, Bates ZHP01344159 through 1344164, was received and marked for identification.)
Q. And one of the things the FDA said in that letter to ZHP was, "You failed to adequately assess the potential formation of mutagenic impurities when you implemented the new process," and they're talking there about the zinc chloride process.
"Specifically, you did not consider the potential for mutagenic or other toxic impurities to form from DMF degradants, including the primary DMF degradant, dimethylamine."
I'm going to stop there. Do you agree with that, that there was a failure to adequately assess?
MR. BERNARDO: Object to the form of the question, foundation.
A. Yes, I agree.
Q. And with regard to the TEA process with sodium nitrite quenching, would your opinion be the same with regard to the substances used in that process?
A. Yes.

Page 298

Q. The FDA also said to ZHP directly in the warning letter to ZHP, "You also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in your valsartan API before you approved the process change. You are responsible for developing and using suitable methods to detect impurities when developing, and making changes to, your manufacturing processes. If new or higher levels of impurities are detected, you should fully evaluate the impurities, and take action to ensure the drug is safe for patients." I'm going to stop there.

Are you in agreement with that?

A. Yes.

MR. BERNARDO: Object to the form -- Doctor, just give me a minute to put my objection on the record.

Object to the form of the question, foundation.

Go ahead.

Q. Is that fully consistent with your opinion that ZHP failed to ensure that they anticipated and detected the NDMA and NDEA that came from their -- these two processes we're talking

Page 299

about?

MR. BERNARDO: Same objection.

A. Yes.

Q. The FDA then said, "Your response," referring to the response from ZHP to the 483 letters that they got from the FDA, "Your response states that predicting NDMA formation during the valsartan manufacturing process required an extra dimension over current industry practice, and that your process development study was adequate. We disagree."

So I'm going to stop there. Do you also disagree with that position taken by ZHP, and their expert, for that matter?

MR. BERNARDO: Same objection.

A. Yes.

Q. And is that for the reasons you're explained during the deposition, in terms of what you thought they should have done in their assessment?

A. They should have known.

Q. And then the FDA says, "We remind you that common industry practice may not always be consistent with Current Good Manufacturing Practice requirements, and that you are responsible for the quality of drugs you produce."

With regard to that statement by the

Page 300

FDA, if ZHP had performed the assessment that you have testified in your opinion they should have, would they have identified the NDMA and NDEA from these two processes from the very beginning, before they even went to market?

MR. BERNARDO: Same objection.

A. Yes, they would have.

Q. And if they had applied that assessment with regard to every batch manufactured going forward, would they have also, in your opinion, identified the NDMA and NDEA from these processes?

A. Yes.

Q. Let's go to your report of July 6, 2021, page 19, please. Okay. Looking at the bottom of page 19 of your July 6, 2021, report, you state, "Once the presence of NDMA was discovered, it was not difficult to determine the root cause. A July 27, 2017, email within ZHP refers to the root cause: Specifically, the fact that NDMA was known to occur in valsartan as a result of the use of sodium nitrite in the sodium azide quenching process, and that there was a need for 'the optimization of the valsartan sodium azide quenching process.'"

Do you see that?

A. Yes.

Page 301

Q. And there's a reference there, 91; and I'm going to 91, which is "Min Li deposition transcript, April 20, 2021, page 82, line 14 to page 90, line 2."

And I just want to confirm that the -- am I correct that the source of that information was the sworn testimony of Min Li, who, during the deposition, confirmed what that email from Jin Shiang Lin said?

A. Yes.

Q. And the fact stated in that email that the sodium nitrite -- let me -- one second, let me just catch my -- new question.

Looking at the email itself, as discussed by Min Li, where it states that "there's n-nitrosodimethylamine that occurs in valsartan when quenched with sodium nitrite, and its structure is very toxic."

With regard to that statement in terms of the root cause for the creation of NDMA in valsartan, is that a correct statement of why it occurred, in terms of the quenching with sodium nitrite?

A. Yes.

Q. And with regard to the TEA process with

Page 302

sodium nitrite quenching, would the same hold true in terms of the root cause?
A. Yes.
Q. Now, what I'd like to do is put up on the screen an article.
MR. SLATER: And my guess is, we're going to need to give this to the defense lawyers, because I don't think that you've seen this. It's something that we --
MR. GEDDIS: I'm putting it in the Dropbox link, and I'm putting it in the chat.
MR. SLATER: Oh, good. Is that okay, everybody?
You are muted, my friend.
MR. BERNARDO: I can see it, but I'd like to have a copy so I can --
MR. SLATER: Yeah, Chris just said he dropped it into the chat, I think.
MR. GEDDIS: No, Dropbox, and I put the DropBox link and in the chat.
MR. SLATER: He's putting in the Dropbox in the chat.
(A discussion is held off the record.)
MR. SLATER: Yep. Do you want us to wait a second while you access that?

Page 303

MR. BERNARDO: Yes, please.
MR. SLATER: Yeah, no problem.
MR HARKINS: Sorry. I'm getting content blocking trying to open that in Dropbox. Is there anywhere else that we've gotten this?
(Court Stenographer clarification.)
MR. HARKINS: Apologies, this is Steve Harkins for Teva.
I'm getting a content filtering message for your Dropbox. I'm just wondering if there was anywhere that this is, or has been sent.
MR. BILY: It's marked on Exhibit Share now, Exhibit 28.
MR. SLATER: Let me know when you all are able to see it. Any luck?
MR. BERNARDO: I have it.
MR. SLATER: Okay, great. Is it okay if I proceed?
MR. BERNARDO: From my perspective. I'll defer to my co-defendants.
MR. SLATER: Steve, is it okay if I get moving?
MR HARKINS: Sorry, I'm still not happy. This isn't on the doctor's reliance list, is it?
MR. SLATER: No, it's not. Although

Page 304

we're supplementing it through this deposition.
MR HARKINS: Sorry. I have a folder for that.
MR. SLATER: Is it all right if I proceed now? Hearing no objection, okay.
BY MR. SLATER:
Q. Doctor --
MR. SLATER: This is Exhibit 28, you said, Chris?
(Exhibit Hecht-28, Article entitled "Identification and Control of Impurities for Drug Substance Development using LC/MS and GC/MS," from The Journal of Liquid Chromatography and Related Technologies, was received and marked for identification.)
BY MR. SLATER:
Q. Doctor, what we've put on the screen as Exhibit 28 is an article that frankly, we pulled during your deposition when you were being questioned about whether or not drug companies would be expected to have LC-MS and GC-MS methodologies available to them, and the equipment to perform that, prior to 2011, 2012, 2013; the time period when the development of these processes occurred. And thereafter.

Page 305

On the screen is an article titled "Identification and Control of Impurities For Drug Substance Development Using LC-MS and GC-MS," which was published in 2008, in The Journal of Liquid Chromatography and Related Technologies.
Do you see that?
A. Yes.
Q. And the authors, Heewon Lee, Sherry Shen, and Nelu Grinberg, apparently worked in the Chemical Development Department at Boehringer Ingelheim Pharmaceuticals in Ridgefield, Connecticut.
Do you see that?
A. Yes.
Q. And the abstract -- and I'm only going to ask you about the first page, frankly -- says at the top, in the beginning, "Identification and control of impurities for drug substances is a critical task in pharmaceutical process development for quality and safety."
And just that general principle you agree with. Correct?
A. Yes.
MR. BERNARDO: Object to form -- let me just put my objection on to the use of an article that was pulled -- and we'll determine who pulled

Page 306

it -- during Dr. Hecht's deposition, that was not part of his reliance material, or otherwise disclosed in advance of the deposition. But go on, Adam.

MR. SLATER: Yeah. The article was pulled by Christopher Geddis, who is the lawyer who's working on this deposition with me, while Dr. Hecht was being questioned.

It's a line of questioning that we didn't really anticipate, so we addressed it while the deposition was happening.

BY MR. SLATER:

Q. Now, looking at the abstract, at the last five lines, it says, "Three case studies are described where unknown process impurities were analyzed for identification using LC-MS and GC-MS methodologies. It is demonstrated that identification of the unknown impurity enabled chemists to pinpoint the chemical step of impurity generation, aiding the effort to reduce or even eliminate the impurity in the drug substances."

Do you see what I just read?

A. Yes.

Q. Is this the type of literature you were stating that you believed was readily available in the scientific literature, demonstrating that drug

Page 307

companies did actually maintain LC-MS and GC-MS technology, prior to the development of the TEA with sodium nitrite quenching and zinc chloride processes were developed?

A. Yes.

MR. BERNARDO: Object to the form of the --

A. Absolutely, this is the type of literature. There's no doubt that drug companies had this technology available.

MR. BERNARDO: Object to the form of the question, and object to the characterization of the prior testimony.

A. It's absolutely consistent with what I was saying.

MR. SLATER: Chris, let's go to the next document, which will be the valsartan analysis report for peak identification.

MR. BERNARDO: I'm sorry, can you repeat what we're going to?

MR. SLATER: I'm talking to Chris. He's going to bring it up on the screen and give it to you all.

(A discussion is held off the record.)

MR. SLATER: He's putting it in the

Page 308

Dropbox first, then he'll put it on the screen, so that you guys can get it, and then when you have it, I can start asking about it.

(Exhibit Hecht-29, Document entitled "Valsartan, Analysis Report for Peak Identification in GC Chromatogram Other Than Listed Solvents," Bates ZHP01746277 through 1746288, was received and marked for identification.)

MR. SLATER: Great. Is this Exhibit 29? Great.

Q. So we're marking this as Exhibit 29. It's titled, "Valsartan analysis report for peak identification in GC chromatogram, other than listed solvents." And I can represent to you, based on the metadata, that this goes back to 2009, this document.

And you can see, you'll be able -- defense counsel will be able to see that there's actually the chromatograms that are discussed go back to -- they're dated; you can see the dates in 2009.

MR. SLATER: And if we go now to the second page of this, which is page 2 of 12, please. Let's blow that up, because that is small. Great.

Q. In this analysis report from 2009 at ZHP, it states that "For residual solvent method, observed extra peaks in the region of about six to

Page 309

eight minutes, which are observed in GC chromatogram available in valsartan batch analysis. The identification of extra peaks, other than listed solvent peaks, are conducted by" -- ZHP.

"The analytical method for residual solvents determination was developed by a head-space GC method. Based on actual two peaks raised at five to seven minutes, we have performed GC-MS, and got the same value of 102 with reference to the solvents' structure." And I'm going to just stop there.

Does this confirm, based on what the language says right there, that ZHP in 2009 had GC-MS technology available to it?

MR. BERNARDO: Object to the form of the question, lack of foundation.

Go ahead.

A. Yes, it confirms.

Q. And is that consistent with your opinion that you would expect a company like ZHP to have had this technology?

A. Yes.

MR. HARKINS: Object to form, leading.

MR. SLATER: Let's go now to the next one, the qualitative report, please. And we'll make that Exhibit 30.

Page 310

(Exhibit Hecht-30, Qualitative Reports, Bates SYNCOR00001458 through 1465, was received and marked for identification.)
(Court Stenographer clarification.)
MR. BERNARDO: Richard Bernardo did.
MR. SLATER: I think Steve Harkins had one too.
MR. HARKINS: Yes, Steve Harkins for Teva.
(Court Stenographer clarification.)
MR. SLATER: It was Mr. Bernardo, and also Steve Harkins objected.
I'm here for you, Steve, just like I'm here for Rich.
MR. BERNARDO: And we so appreciate it, Adam.
MR. SLATER: Okay.
BY MR. SLATER:
Q. Looking at Exhibit 30, which is a qualitative report dated November -- November 19, 2012, does this show a printout of GC-MS chromatograms? Do you see the GC-MS method is indicated at the top?
A. Yes.
Q. So does this show, consistent with your

Page 311

understanding, that ZHP had GC-MS technology available to it, at least as of 2012?
A. Yes.
Q. Okay.
MR. SLATER: Let's take that down, and let's go to the next exhibit, which is going to be a PowerPoint. And I'll just say for the record, the Bates number is SOLCO 00027588. And it's a PowerPoint dated August 23, 2012, from ZHP.
(Exhibit Hecht-31, PowerPoint Presentation dated August 23, 2012, No Bates, 19 Slides, was received and marked for identification.)
MR. SLATER: And let's go to -- I don't know how to number the pages, but it's I think the fourth or fifth to last page, which has a listing of research and development capabilities, listing analytical instruments and capabilities at ZHP.
Q. And if you look down, it says "mass spectrometry." And do you see it lists two different types of mass spectrometry?
A. Yes.
Q. "LC-MS Agilent 1100, GC-MS Agilent 7890A." Are those both mass spectrometers of the nature -- of the type that you would have expected, as you testified earlier, a company like ZHP would

Page 312

have had available to it?
A. Yes.
Q. And Doctor, I just want to make one more thing clear. Today you were asked a lot of questions about the zinc chloride process.
With regard to your fundamental opinions about why it happened, the availability of the literature, if a reasonable scientific review was done in order to understand the risks of that procedure, and the methodology and capability to test for NDMA and NDEA; would all of your opinions, as you gave them regarding the zinc chloride process, apply to the TEA with sodium nitrite quenching process?
A. Yes.
MR. SLATER: I have no other questions, thank you.
MR. BERNARDO: Dr. Hecht, just a few follow-ups.
EXAMINATION BY MR. BERNARDO:
Q. First, I want to talk about the July 2017 Jin Shiang Lin memo that Mr. Slater was asking about a moment ago. Do you know what document I'm talking about?
A. Yep.
Q. Okay. And you cite to testimony of one

Page 313

individual, Min Li. Correct?
A. Yes.
Q. And what's your understanding -- first of all, did Min Li write that document? The July --
A. No, I think Jin Shiang Lin wrote it.
Q. Did you read any testimony or interviews, or otherwise have any understanding of what Jin Shiang Lin's statements as to the meaning of that memo would be?
MR. SLATER: Objection.
You could answer.
A. I don't remember.
Q. Okay. What is your understanding or recollection of what Dr. Li testified, what's your understanding of that memo, from Dr. Li's testimony?
MR. SLATER: Objection, it's ambiguous.
A. This is from Jin Shiang Lin. I'm lost here. I mean, what are you asking me?
Q. Mr. Slater was pointing out to you that in your report, you're citing to testimony of Dr. Li as to what that memo means. Is that right?
A. Yes.
Q. And I'm asking you, what is your understanding, based upon the testimony of Dr. Li, of what that memo means?

Page 314

A. Well --
Q. And you can use your report, Doctor. You can also reference that if you want to?
A. I mean, what it means is that, you know, there was -- that they had identified dimethylnitrosamine in valsartan. I mean, that's what this says.
Q. And that's your understanding of what Dr. Li testified about?
A. Yeah.
Q. And Dr. Li didn't write the memo. Is that fair?
A. No, the memo was written by Lin.
Q. And did you read any testimony of any other individuals at ZHP who testified about what that memo means?
A. I don't remember.
Q. Well, okay. Mr. Slater -- different topic. Mr. Slater pulled up an article during your deposition with respect to a couple of the issues about which we've talked. I want to talk about the first article that was pulled up.
MR. BERNARDO: And if we could pull that one up again, Adam or Chris, whoever was pulling that up.

Page 315

MR. SLATER: Yeah, sure, let's pull it up.
Q. And this is not an article that you read or relied on in connection with your report or your opinions previous to today. Is that fair?
A. Correct.
Q. And this is a report that talks about the availability of this type of testing. Is that correct?
A. Instrumentation, yes.
Q. Correct, okay. But it doesn't speak to what would be used in what circumstances, or what was standard in the industry to use in particular circumstances. Is that fair?
MR. SLATER: Objection.
You can answer.
A. Well, I haven't read the article, but...
Q. So if you haven't read the article, then it's clearly not something you're relying with respect to your testimony. It's something that Mr. Slater just showed you here. Correct?
MR. SLATER: Objection.
You can answer.
A. I'm relying on my knowledge of the field of mass spectrometry. And when I said that this

Page 316

instrumentation was widely available in the pharmaceutical industry at the time when all this was happening, that's a fact. And this just confirms it.
Q. It confirms that it was available, Dr. Hecht, but does it confirm that it would be the type of testing or spectrometry that would be used, under the circumstances of the type of testing that was being done by ZHP or any other manufacturer?
A. Of course it would be used.
Q. Well, let me --
A. Because it's -- you know, it's better than just GC-FID, and it's better than LC with UV detection. So of course it would be used.
Q. In certain types of circumstances, it would be better. Correct?
A. Yes.
MR. SLATER: Objection.
You could answer.
A. Right, that's true.
Q. So neither this article nor the other documents that Mr. Slater showed you from ZHP'S files would necessarily show that this was the better type to use, under the type of testing that was being done of valsartan in the routine testing. Is that fair?
MR. SLATER: Objection to the question.

Page 317

You can answer.
A. Novartis used it, so I mean...
Q. In 2018?
A. This is really -- I mean -- professional chemists want to use the best available technology, and the industry certainly wants to get the best available technology to analyze their products.
And, you know, what this says is that technology was clearly available in -- when was this published? 2009.
This is just consistent with what I've been saying all along: That the technology has been available since the early 2000s. The LC-MS technology -- after electro-spray came out, LC-MS took off, all right? And, you know, before that, I mean, GC-MS was available since the 1970s.
So I mean, to propose that the pharmaceutical industry didn't have access to this instrumentation is almost laughable.
Q. Dr. Hecht, we're not talking about what was available; we're talking about what would have been typically used, under the type of testing that was done. Right?
A. Yep.
Q. And this -- neither this article nor the

Page 318

documents from ZHP show that this type of technology, despite its availability, would have been industry standard to use, in the type of testing that was being done; rather, it would show that it was available technology. Is that fair?

MR. SLATER: Objection.

You can answer.

A. If it's available, it will be used, believe me.

Q. All right.

MR. SLATER: I don't have any further questions, Dr. Hecht.

MR HARKINS: I'm sorry. Just one clarification for the record, Dr. Hecht.

EXAMINATION BY MR HARKINS:

Q. Looking at that article that you reviewed, or I'm sorry, that article that you did not review; can you read the second sentence from the abstract?

A. No, you have to make it larger.

Q. I apologize, I don't have control of it.

A. The second sentence says, "The most commonly used analytical technique for impurity analysis in drug substances and drug products is undoubtedly the chromatographic method, namely HPLC."

Page 319

Q. Do you dispute that sentence?

A. Not at all, because most --

MR HARKINS: That's all I have.

A. Most things that they would be analyzing for -- not most things, but many things that they would not -- that they would be analyzing for, you couldn't do by GC, because they're not volatile. So that's why LC-MS, the use of it, exploded after the development of the electro spray interface, which was around 2000, which I believe somebody got the Nobel Prize for. So, you know, LC-MS took over the field after electro spray came along.

So, you know, those are just the facts. And I mean, to propose that the industry didn't have this instrumentation is nonsense.

Q. Dr. Hecht, my question was just: Do you agree with the statement in this article that -- while you have not read, you are apparently relying on for your opinion -- that "the most commonly-used analytical technique for impurity analysis in drug substances and drug products is undoubtedly a chromatographic method, namely high-performance liquid chromatography, HPLC."

Do you agree with that?

A. Yes, HPLC, yeah. Coupled -- I mean, you

Page 320

have to have a detection system. So this is not saying, you know, what the detection system is.

HPLC stands for high-performance liquid chromatography; that's the separation system. Then the HPLC has to be connected to a detector of some sort. And that could be UV detection, or that could be mass spec detection.

MR HARKINS: No questions.

MR. SLATER: I just have one follow-up.

Chris, could you scroll to the next page, please. Yes, perfect.

EXAMINATION BY MR. SLATER:

Q. Doctor, at the middle of the second page of this article, which is page 2236, it states, "Identification and tracking of organic impurities using LC-MS-related technologies for drug substance and drug product development is well-documented in the literature," and you see that there's citations from 3 to 12 and 13 to 16. Do you see that?

A. Yep.

Q. And is that consistent with your opinion that the use of this technology would have been well-documented in the literature?

A. Absolutely.

Q. And that's -- it states "for drug

Page 321

substance and drug product development." That would apply to what we're talking about in this case. Right?

A. Yes.

Q. And if we go to the next page, 2237, the second full paragraph, the end of that paragraph.

MR. SLATER: Scroll up a little bit, Chris. All right, perfect. No, no, don't go any further. Yeah, a little more. I want to see more of the bottom of the page. Okay, perfect.

Q. Towards the bottom of the page, there's a paragraph that starts "most drug substances."

Do you see that?

A. Yes.

Q. The last sentence of that paragraph says, "Especially, GC-MS is a powerful analytical technique for identification of unknowns, due to the availability of vast and accessible spectral libraries."

What does that mean, that there are "vast and accessible spectral libraries" available, as they're stating there?

MR. BERNARDO: Object to the form of the question, foundation.

A. Exactly what it says. I mean, there are

Page 322

vast libraries that show the mass spec fragmentation pattern of, you know, thousands of compounds. So you can take your output from the GC-MS, which will be a mass spectrum, and compare to the database to, you know, get a possible match.

Q. And again, is that consistent with the opinion you provided in your deposition that, to your understanding, that this technology was available and utilized in the drug development and drug manufacturing industry, before the TEA with sodium nitrite and zinc chloride processes were developed, and all throughout the time that they were used, up until 2018?

A. Yes, it was available.

MR. SLATER: I have no other questions.

MR. BERNARDO: I have one last.

EXAMINATION BY MR. BERNARDO:

Q. Dr. Hecht, I just want to clarify something for the record, because I don't think those words came out of your mouth; but rather, plaintiff's counsel's mouth.

The article that we're looking at is not one that you researched and identified, for purposes of your opinion or forming your opinions. Correct?

A. Correct.

Page 323

Q. It's one that plaintiff's counsel, during your deposition, found and is asking you questions about, because they're asking you questions to determine whether this article is consistent with your testimony. Is that correct?

MR. SLATER: Objection.

A. Yeah, I didn't need the article. I mean, I've been doing this 40 years.

Q. I just want to clarify --

A. I know the field. I didn't need to read this article to tell me that the pharmaceutical industry has mass spectrometers.

Q. I didn't ask that question. I simply wanted to know, from a logistical standpoint, that this was something that you didn't identify, but plaintiff's counsel identified for you, during your deposition. Is that correct?

A. Correct.

MR. BERNARDO: Thank you. I have no further questions and --

MR. SLATER: One last question.

EXAMINATION BY MR. SLATER:

Q. Now that you've seen this -- well, rephrase. Just to be very clear.

Is this article consistent and

Page 324

confirming -- confirmatory of the opinion you gave earlier in the deposition, regarding the availability and use of these technologies?

A. Yes.

Q. And now that you have the article, is it something that you would rely on, if you testified at trial, to support that opinion?

A. Yes.

MR. SLATER: No other questions.

MR. BERNARDO: I don't want to take some time.

EXAMINATION BY MR. BERNARDO:

Q. But Dr. Hecht, you have not read this article in the last few minutes that we've been talking about it. Correct?

A. I saw the abstract.

Q. You read the abstract?

A. Yes.

Q. Wouldn't you first want to read the entire article, to determine if it's one on which you would rely to form your opinion, or do you just read an abstract and determine that this is --

A. No, I could read the whole article.

Q. But you didn't read the whole article. Correct?

Page 325

A. No, I didn't read the whole article. I didn't need to, because I know this stuff. I could have written that article.

Q. But you didn't?

A. No.

Q. And you didn't read the article?

A. No, I didn't read the article.

MR. BERNARDO: Sorry, Steve.

MR HARKINS: No.

EXAMINATION BY MR HARKINS:

Q. Just to confirm, Dr. Hecht, are you able to identify any article that you have actually read, either in your materials cited in support of your opinions, or that you can identify to us now, in support of this point?

A. Well, much of my work that's cited in my CV, which I think you have, relies on these methods. I'm not in the pharmaceutical industry, but it's the same thing: You're looking at complex mixtures by GC-MS or LC-MS to identify specific substances, including dimethylnitrosamine.

So no, I don't work in the pharmaceutical industry; and no, I didn't use GSMC and LC-MS to identify compounds, contaminants, minor constituents of pharmaceutical products; but I used

it for -- to identify minor constituents of other products, like tobacco. So it's the same principle.

And, you know, I was at a small foundation. We had to stretch to spend the money to get the instrumentation, GC-MS and LC-MS. You know, to propose that the pharmaceutical industry did not have access to this instrumentation at the time when all this was going is -- it's absolutely wrong. They absolutely had access, and used it.

Q. Doctor, I think you might have been confused by my question. I'm asking if you can identify, or have identified in connection with either of your reports, any article that you have actually read to support the proposition that this was widespread in the pharmaceutical industry?

A. No, I did not.

MR HARKINS: No further questions.

MR. SLATER: I have no other questions.

MR. BERNARDO: Thank you very much, Dr. Hecht, for your time. I hope your snow dissipates.

THE WITNESS: Thank you.

THE VIDEOGRAPHER: We're off the record at 4:55 p.m. Central Time, and this concludes today's testimony given by Dr. Stephen Hecht. The total

number of media used was seven, and will be retained by Veritext.

(The proceedings concluded at 4:55 p.m. CST.)

J U R A T

I DO HEREBY CERTIFY that I have read the foregoing transcript of my deposition testimony and I certify that is it true and correct to the best of my knowledge.

_____

STEPHEN HECHT

Subscribed and sworn to before me

this __ day of _____, 2023.

_____

Notary public

C E R T I F I C A T E

I, ELLEN J. GODINO, LICENSE NO. Xl0l6l8, a Certified Shorthand Reporter of the State of New Jersey, do hereby certify that prior to the commencement of the examination, STEPHEN HECHT, Ph.D. was duly sworn by me to testify the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

Ellen J. Godino

ELLEN J. GODINO
CERTIFIED COURT REPORTER
State of New Jersey
DATED: 1/18/23

ERRATA SHEET
VERITEXT/NEW YORK REPORTING, LLC

CASE NAME: In Re: Valsartan, Losartan, Et Al v.
DATE OF DEPOSITION: 1/13/2023
WITNESSES' NAME: Stephen Hecht , M.D.

PAGE	LINE (S)	CHANGE	REASON

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Stephen Hecht , M.D.

SUBSCRIBED AND SWORN TO BEFORE ME
THIS ____ DAY OF _____, 20__.

_____ _____
(NOTARY PUBLIC) MY COMMISSION EXPIRES:

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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